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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 1146 and 1147

[Doc. No. AMS–DA–21–0013]

RIN 0581–AE00

Dairy Donation Program

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule; removal of expiration date.

SUMMARY: On September 1, 2021, the Agricultural Marketing Service (AMS) amended the provisions of the Milk Donation Reimbursement Program through September 1, 2023, and added regulations for the Dairy Donation Program, on an interim basis, set to expire September 1, 2023. On August 24, 2023, AMS published a final rule further amending the provisions of both programs and removing the expiration date for the Dairy Donation Program. However, we failed to formally adopt the interim provisions, remove the expiration of the amendments to the Milk Donation Reimbursement Program, and list the removal of both expirations in the **DATES** section of the preamble. This final rule corrects that oversight.

DATES: Effective August 31 2023, the September 1, 2023, expiration date for the amendments to §§ 1146.1, 1146.102, 1146.106, and the addition of part 1147, published September 1, 2021, at 86 FR 48887, is removed.

FOR FURTHER INFORMATION CONTACT: Erin Taylor, Director, Order Formulation and Enforcement, AMS Dairy Program, USDA; 1400 Independence Avenue SW, Room 2524–S, Washington, DC 20250; telephone: (202) 720–7311; email: *DDP@usda.gov;* web address: *www.ams.usda.gov/ddp*.

SUPPLEMENTARY INFORMATION: The Dairy Donations Program (DDP) was implemented on September 1, 2021, through an interim final rule (86 FR 48887). The final rule of August 25, 2023 (88 FR 57861), finalized and made minor changes to the provisions of the DDP codified at 7 CFR part 1147. The final rule of August 25, 2023, also further amended the provisions of the Milk Donation Reimbursement Program (MDRP), which was established in 2021 (84 FR 46658), and amended in 2021 (86 FR 48897) to better coordinate with the DDP. Both donation programs provide for reimbursement of certain costs for donations of milk and dairy products and help reduce food waste.

The DDP and the 2021 amendments to MDRP were set to expire September 1, 2023. However, AMS determined to retain both programs as established and amended and to further amend certain provisions of both parts. The final rule of August 25, 2023, made further amendments to both parts and removed expiration of the DDP provisions, but failed to remove expiration of the 2021 amendments to the MDRP. This document corrects that oversight.

7 CFR PART 1146—MILK DONATION REIMBURSEMENT PROGRAM

7 CFR PART 1147—DAIRY DONATION PROGRAM

■ AMS adopts as final the interim rule amending 7 CFR parts 1146 and 1147 which was published at 86 FR 48887 on September 1, 2021, with the changes published at 88 FR 57861 on August 24, 2023.

Erin Morris,

Associate Deputy Administrator, Agricultural Marketing Service.

[FR Doc. 2023–18949 Filed 8–30–23; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2021–BT–STD–0035]

RIN 1904–AF46

Energy Conservation Program: Energy Conservation Standards for Air Cleaners

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Direct final rule; confirmation of effective and compliance dates.

SUMMARY: The U.S. Department of Energy (''DOE'') published a direct final rule to establish new energy conservation standards for air cleaners in the **Federal Register** on April 11, 2023. DOE has determined that the comments received in response to the direct final rule do not provide a reasonable basis for withdrawing the direct final rule. Therefore, DOE provides this document confirming adoption of the energy conservation standards established in the direct final rule and announcing the effective date of those standards.

DATES: The effective date of August 9, 2023, for the direct final rule published April 11, 2023 (88 FR 21752) is confirmed. Compliance with the new standards established in the direct final rule will be required on December 31, 2023.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *www.regulations.gov*. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE-2021-BT-STD-0035*. The docket web page contains instructions on how to access all documents, including public comments, in the docket.

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov*.

FOR FURTHER INFORMATION CONTACT:

Mr. Troy Watson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 449–9387. Email: *ApplianceStandardsQuestions@ee.doe.gov*.

Ms. Amelia Whiting, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–2588. Email: *Amelia.Whiting@hq.doe.gov*.

SUPPLEMENTARY INFORMATION:

I. Authority

The Energy Policy and Conservation Act, Public Law 94–163, as amended (''EPCA''),[1] authorizes DOE to issue a direct final rule establishing an energy conservation standard for a product on receipt of a statement submitted jointly by interested persons that are fairly representative of relevant points of view (including representatives of manufacturers of covered products, States, and efficiency advocates), as determined by the Secretary, that contains recommendations with respect to an energy or water conservation standard that are in accordance with the provisions of 42 U.S.C. 6295(o) or 42 U.S.C. 6316, as applicable. (42 U.S.C. 6295(p)(4))

The direct final rule must be published simultaneously with a notice of proposed rulemaking (''NOPR'') that proposes an energy or water conservation standard that is identical to the standard established in the direct final rule, and DOE must provide a public comment period of at least 110 days on this proposal. (42 U.S.C. 6295(p)(4)(A)–(B)) Not later than 120 days after issuance of the direct final rule, DOE shall withdraw the direct final rule if (1) DOE receives one or more adverse public comments relating to the direct final rule or any alternative joint recommendation; and (2) based on the rulemaking record relating to the direct final rule, DOE determines that such adverse public comments or alternative joint recommendation may provide a reasonable basis for withdrawing the direct final rule. (42 U.S.C. 6295(p)(4)(C)) If DOE makes such a determination, DOE must proceed with the NOPR published simultaneously with the direct final rule and publish in the **Federal Register** the reasons why the direct final rule was withdrawn. *Id.*

DOE determined that it did not receive any adverse comments providing a basis for withdrawal described above for the direct final rule that is the subject of this document—air cleaners. As such, DOE did not withdraw this direct final rule and allowed it to become effective. Although not required under EPCA, DOE customarily publishes a summary of the comments received during the 110-day comment period and its responses to those comments. This document contains such a summary, as well as DOE's responses, for air cleaners.

II. Air Cleaners Direct Final Rule

Air cleaners are not currently subject to Federal energy conservation standards. On January 25, 2022, DOE published a request for information (''January 2022 RFI''), seeking comments on potential test procedure and energy conservation standards for air cleaners. 87 FR 3702. In the January 2022 RFI, DOE requested information to aid in the development of the technical and economic analyses to support energy conservation standards for air cleaners, should they be warranted. *Id.*

In a final determination published on July 15, 2022 (''July 2022 Final Determination''), DOE determined that coverage of air cleaners is necessary or appropriate to carry out the purposes of EPCA; the average U.S. household energy use for air cleaners is likely to exceed 100 kilowatt-hours per year (''kWh/yr''); and thus, air cleaners qualify as a ''covered product'' under EPCA. 87 FR 42297.

On August 23, 2022, DOE received a proposal jointly submitted by groups representing manufacturers, energy and environmental advocates, and consumer groups, hereinafter referred to as ''the Joint Stakeholders.'' [2] This proposal, titled ''Joint Statement of Joint Stakeholder Proposal On Recommended Energy Conservation Standards And Test Procedure For Consumer Room Air Cleaners'' (hereafter, the ''Joint Proposal'' [3]), recommended specific energy conservation standards for air cleaners that, in the commenters' view, would satisfy the EPCA requirements in 42 U.S.C. 6295(o). The Joint Proposal urged DOE to publish final rules adopting the consumer room air cleaner test procedure and standards and compliance dates contained in the Joint Proposal, as soon as possible, but not later than December 31, 2022. (Joint Stakeholders, No. 16 at p. 1) The Joint Proposal also recommended that DOE adopt industry standard AHAM AC–7–2022 [4] as the DOE test procedure. (*Id.* at p. 6) In regard to energy conservation standards, the Joint Proposal specified two-tiered (*i.e.,* Tier 1 and Tier 2) standard levels, as shown in Table II.1, for conventional room air cleaners with proposed compliance dates of December 31, 2023, and December 31, 2025, respectively. (*Id.* at p. 9).

TABLE II.1—TIER 1 AND TIER 2 STANDARDS PROPOSED BY THE JOINT STAKEHOLDERS IN THE JOINT PROPOSAL

Product description	IEF ($PM_{2.5}$ CADR/W) Tier 1 *	IEF ($PM_{2.5}$ CADR/W) Tier 2 **
$10 \leq PM_{2.5}$ CADR < 100	1.69	1.89

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] The Joint Stakeholders include the Association of Home Appliance Manufacturers (''AHAM''), Appliance Standards Awareness Project (''ASAP''), American Council for an Energy-Efficient Economy (''ACEEE''), Consumer Federation of America (''CFA''), Natural Resources Defense Council (''NRDC''), the New York State Energy Research and Development Authority (''NYSERDA''), and the Pacific Gas and Electric Company (''PG&E''). AHAM is representing the companies who manufacture consumer room air cleaners and are members of the Portable Appliance Division (DOE has included names of all manufacturers listed in the footnote on page 1 of the Joint Proposal and the signatories listed on pages 13–14): 3M Co.; Access Business Group, LLC; ACCO Brands Corporation; Air King, Air King Ventilation Products; Airgle Corporation; Alticor, Inc.; Beijing Smartmi Electronic Technology Co., Ltd.; BISSELL Inc.; Blueair Inc.; BSH Home Appliances Corporation; De'Longhi America, Inc.; Dyson Limited; Essick Air Products; Fellowes Inc.; Field Controls; Foxconn Technology Group; GE Appliances, a Haier company; Gree Electric Appliances Inc.; Groupe SEB; Guardian Technologies, LLC; Haier Smart Home Co., Ltd.; Helen of Troy-Health & Home; iRobot; Lasko Products, Inc.; Molekule Inc.; Newell Brands Inc.; Oransi LLC; Phillips Domestic Appliances NA Corporation; SharkNinja Operating, LLC; Sharp Electronics Corporation; Sharp Electronics of Canada Ltd.; Sunbeam Products, Inc.; Trovac Industries Ltd; Vornado Air LLC; Whirlpool Corporation; Winix Inc.; and Zojirushi America Corporation.

[3] The Joint Proposal is available in the docket for this rulemaking at *www.regulations.gov/comment/EERE-2021-BT-STD-0035-0016*.

[4] AHAM AC–7–2022 Energy Test Method for Consumer Room Air Cleaners. Available for purchase at: *https://www.aham.org/ItemDetail?iProductCode=37002&Category=PADSTD&websiteKey=c0a5e5a1-ea1c-42f1-9b84-d62256c16ea2*.

TABLE II.1—TIER 1 AND TIER 2 STANDARDS PROPOSED BY THE JOINT STAKEHOLDERS IN THE JOINT PROPOSAL—Continued

Product description	IEF ($PM_{2.5}$ CADR/W) Tier 1 *	IEF ($PM_{2.5}$ CADR/W) Tier 2 **
100 ≤ $PM_{2.5}$ CADR < 150	1.90	2.39
$PM_{2.5}$ CADR ≥ 150	2.01	2.91

* Tier 1 standards would have a compliance date of December 31, 2023.
** Tier 2 standards would have a compliance date of December 31, 2025.

After carefully considering the consensus recommendations for establishing energy conservation standards for air cleaners submitted by the Joint Stakeholders, DOE determined that these recommendations were in accordance with the statutory requirements of 42 U.S.C. 6295(p)(4) for the issuance of a direct final rule and published a direct final rule on April 11, 2023 (''April 2023 Direct Final Rule''). 88 FR 21752, 21760. DOE also evaluated whether the recommendation satisfies 42 U.S.C. 6295(o), as applicable, and found that the Joint Proposal recommended standard levels would result in significant energy savings and are technologically feasible and economically justified. 88 FR 21752, 21753. Accordingly, the consensus-recommended efficiency levels for air cleaners were adopted as the new standard levels in the April 2023 Direct Final Rule.[5] 88 FR 21752, 21807–21810.

These standards, which are expressed as an integrated energy factor (''IEF'') in terms of $PM_{2.5}$[6] clean air delivery rate per watt (''$PM_{2.5}$ CADR/W''), based on the product's measured $PM_{2.5}$ CADR. These standards apply to all products listed in Table II.2 and manufactured in, or imported into, the United States starting on December 31, 2023, for Tier 1 standards and on December 31, 2025, for Tier 2 standards. The April 2023 Direct Final Rule provides a detailed discussion of DOE's analysis of the benefits and burdens of the new standards pursuant to the criteria set forth in EPCA. 88 FR 21752.

TABLE II.2—ENERGY CONSERVATION STANDARDS FOR AIR CLEANERS

[Tier 1 compliance starting December 31, 2023; Tier 2 compliance starting December 31, 2025]

Product class	IEF ($PM_{2.5}$ CADR/W)[7]	
	Tier 1 December 31, 2023	Tier 2 December 31, 2025
PC1: 10 ≤ $PM_{2.5}$ CADR < 100	1.7	1.9
PC2: 100 ≤ $PM_{2.5}$ CADR < 150	1.9	2.4
PC3: $PM_{2.5}$ CADR ≥ 150	2.0	2.9

As required by EPCA, DOE also simultaneously published a NOPR proposing the identical standard levels contained in the April 2023 Direct Final Rule. 88 FR 21512. DOE considered whether any comment received during the 110-day comment period following the direct final rule was sufficiently ''adverse'' as to provide a reasonable basis for withdrawal of the direct final rule and continuation of this rulemaking under the NOPR. When making a determination whether to withdraw a direct final rule, it is the substance, rather than the quantity, of comments that will ultimately determine whether a direct final rule will be withdrawn. To this end, DOE weighs the substance of any adverse comment(s) received against the anticipated benefits of the consensus recommendations and the likelihood that further consideration of the comment(s) would change the results of the rulemaking. DOE notes that to the extent an adverse comment had been previously raised and addressed in the rulemaking proceeding, such a submission will not typically provide a basis for withdrawal of a direct final rule.

III. Comments on the Direct Final Rule

As discussed in section I of this document, not later than 120 days after publication of a direct final rule, DOE shall withdraw the direct final rule if (1) DOE receives one or more adverse public comments relating to the direct final rule or any alternative joint recommendation; and (2) based on the rulemaking record relating to the direct final rule, DOE determines that such adverse public comments or alternative joint recommendation may provide a reasonable basis for withdrawing the direct final rule. (42 U.S.C. 6295(p)(4)(C)(i))

DOE received comments in response to the April 2023 Direct Final Rule from the interested parties listed in Table III.1.

[5] The standard levels enacted by the April 2023 Direct Final Rule were rounded to the nearest tenth decimal consistent with the sampling plan requirements in 10 CFR 429.68. The rounding has no functional impact on the standards as compared to the levels proposed in the Joint Proposal.

[6] Section 2.8 of the industry standard AHAM AC–7–2022 defines $PM_{2.5}$ as particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers as measured by a reference method based on 40 CFR part 50 Annex I and designated in accordance with 40 CFR part 53 or by an equivalent method designated in accordance with 40 CFR part 53.

[7] These values from the Joint Proposal are rounded according to the sampling plan in 10 CFR 429.68. The rounding has no functional impact on the standards as compared to the levels in the Joint Proposal.

TABLE III.1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE APRIL 2023 DIRECT FINAL RULE

Commenter(s)	Abbreviation	Comment number in the docket	Commenter type
SENSIRON AG	SENSIRON AG	27	Component Manufacturer.
IQAir North America	IQAir	28	Manufacturer.
Slaughter	Slaughter	29	Individual.
Association of Home Appliance Manufacturers	AHAM	30	Trade Association.
ACEEE, ASAP, AHAM, CFA, NRDC	Joint Stakeholders	31	Individual Efficiency Organizations, Consumer Organization, and Trade Association.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[8] The following sections discuss the substantive comments DOE received on the April 2023 Direct Final Rule as well as DOE's responses.

A. General Comments

In comments submitted in response to the April 2023 Direct Final Rule, the Joint Stakeholders and AHAM expressed support for the standard levels specified in the April 2023 Direct Final Rule as well as the process used to develop those standards. (Joint Stakeholders, No. 31 at pp. 1–2; AHAM. No. 30 at p. 1) The Joint Stakeholders noted their appreciation for DOE's swift action in publishing the DFR and stated their belief that the standards are economically justified and technologically feasible and will achieve significant savings. (Joint Stakeholders, No. 31 at pp. 1–2) DOE appreciates the Joint Stakeholder's comments and agrees that the standards are economically justified and technologically feasible and will result in significant energy savings.

The Joint Stakeholders urged DOE to propose and finalize reporting criteria for air cleaners, especially because compliance with Tier 1 standards would be required beginning December 31, 2023. The Joint Stakeholders stated that manufacturers would need to know the reporting criteria to begin completing their compliance reporting efforts. (Joint Stakeholders, No. 31 at p. 2) DOE acknowledges that certification data will be required for air cleaners; however, DOE did not adopt certification or reporting requirements for air cleaners in the April 2023 Direct Final Rule. Instead, DOE may consider proposals to establish certification requirements and reporting for air cleaners under a separate rulemaking regarding certification for covered products and equipment.

B. Vacuum Cleaners With Air Cleaning Functionality

AHAM commented that vacuum cleaners with a secondary air cleaning function should not be included in the scope of the air cleaners standards or test procedure at 10 CFR part 430, subpart B, appendix FF (''appendix FF''). AHAM noted that there are currently vacuum cleaners available on the market that clean the air as a secondary function simultaneously with the primary vacuuming function. (AHAM, No. 30 at pp. 1–2) AHAM commented that the air filter function for these products is not an independent function of the vacuum cleaner and that the product is not intended to be plugged in on an ongoing basis. For these reasons, AHAM commented that it understands that vacuum cleaners that also clean the air, while vacuuming are not under the scope of this rule or appendix FF. (AHAM, No. 30 at p. 2) AHAM commented that such vacuum cleaners would not meet the proposed standards, and asserted that the Joint Stakeholders had not considered such products in the scope when developing the standards that they presented to DOE in the Joint Proposal. AHAM also noted that it had examined these products as part of the AHAM AC–7–2022 task force and these products would not be in the scope of the AHAM AC–7–2022 standard. (*Id.*) AHAM suggested that DOE clarify that these products are not in the scope of the air cleaner standards via a guidance document. AHAM additionally stated that if these vacuum cleaners are included under the scope, then DOE could amend section 2.2.2 of appendix FF to indicate that if a product has air cleaning as a secondary function and one of the secondary listed functions is a primary function as defined by the product safety certification listing, then the test method would not apply to such products. (*Id.*)

Air cleaners are defined as a product for improving indoor air quality, other than a central air conditioner, room air conditioner, portable air conditioner, dehumidifier, and furnace, that is an electrically-powered, self-contained, mechanically encased assembly that contains means to remove, destroy, or deactivate particulates, VOC [volatile organic compounds], and/or microorganisms from the air. It excludes products that operate solely by means of ultraviolet light without a far for air circulation. 10 CFR 430.2. In the July 2022 Final Determination, DOE noted that the reason for explicitly stating that ''air cleaners are a product for improving indoor air quality'' was to clarify that the term ''air cleaners'' does not include products that may provide some air cleaning as an ancillary function (*e.g.,* a vacuum cleaner). 87 FR 42297, 42302. Accordingly, vacuum cleaners that provide air cleaning as an ancillary function do not meet the definition of an air cleaner.

C. Air Cleaners With Gas Filtration

IQAir North America, Inc. together with Swiss affiliate IQAir AG (collectively ''IQAir''), commented that the standards established in the April 2023 Direct Final Rule would have a permanent negative effect on some of its products and would eliminate an entire class of air purification products. (IQAir, No. 28 at pp. 1, 5) IQAir commented that it makes products for gaseous and odor filtration, including filtration of VOCs. (*Id.* at pp. 1–2) IQAir asserted that gas-phase filtration inherently requires greater energy than simple particulate/HEPA[9] filtration, and that due to the increased energy usage of gas-phase filtration, these products will not meet the IEF levels specified in the direct final rule and therefore will no longer be able to be

[8] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop energy conservation standards for air cleaners. (Docket No. EERE–2021–BT–STD–0035, which is maintained at *www.regulations.gov*). The references are arranged as follows: (commenter name, comment docket ID number, page of that document).

[9] High efficiency particulate air (''HEPA'') filter is a pleated mechanical air filter that includes a porous filtration medium typically composed of randomly arranged polypropylene or fiberglass fibers. As air passes through the porous media, particulates in the air become trapped on the filter surface, allowing clean air to be discharged by the air cleaner.

sold in the United States. (*Id.* at pp. 2–3) IQAir stated that its gas-phase air cleaners have played a vital role for specific segments of the population, such as those effected by natural gas exposure, which contains toxic VOCs and odorous gases. (*Id.* at p. 4) IQAir stated that gas-phase air cleaners are critical to its product lineup and being unable to sell them in the United States would be devastating to its business operations there. (*Id.* at p. 5)

IQAir stated that one of the most effective ways to filter gases and odors is with granular sorbent media such as activated charcoal, and chemisorbant pellets. IQAir noted that its gas-filtration-based products include a proprietary blend of activated carbon and alumina, impregnated with potassium permanganate. (*Id.* at p. 2) IQAir noted that of the three of its products that offer this functionality, the top gas-filtration model is GCX, which includes cartridge-based granular filters containing over 20 pounds of media. IQAir noted that all three of these products meet the definition of an air cleaner as specified in the April 2023 Direct Final Rule, would be subject to the standards established in that direct final rule, and would be tested in the same way as air cleaners that do not offer gas-phase filtration. (*Id.*)

In explaining how gas-phase filtration inherently requires greater energy than simple particulate/HEPA filtration, IQAir stated that pushing air through the pre-filter and varying types and amounts of granular media requires electric motors of a certain power level. IQAir commented that its models have already achieved the best possible energy efficiency at given levels of gas-phase reductions, capacity, and price. IQAir stated that the gas-phase filtration technology contained in its products performs a valuable, sought-after function, and that standard particulate/HEPA systems are physically incapable of performing this same function. IQAir also stated that there is no feasible combination of currently available components or technology that could allow their air cleaners to meet the standards established in the April 2023 Direct Final Rule without going into a price range that is far out of reach of its customers. IQAir requested that DOE consider the importance of the entire class of gas-phase products that it believes will be effectively banned by the standards established in the April 2023 Direct Final Rule. (*Id.* at p. 5) IQAir also asserted that the large capacity of its air cleaners enables more contaminates to be absorbed over a longer period of time before needing filter replacements. (*Id.* at p. 4)

DOE has conducted an extensive review of products that provide gaseous and odor filtration through the use of carbon filter media, including those models referenced in IQAir's comments. Based on this review, DOE has concluded that it is technologically feasible to implement design options to achieve higher levels of efficiency in air cleaners that employ the key design characteristics observed in those models referenced in IQAir's comments. Specifically, DOE observed that the HEPA-type filter included in IQAir's products is up to 6 inches thick and that the units have an inlet/outlet air flow design that restricts airflow by drawing in air over a smaller surface area (compared to the size of the unit) at the base of the model and only allows air to exit over a small surface area at the topmost section of the cabinet. Further, DOE observed that IQAir's products use a permanent split capacitor (''PSC'') fan motor, rather than more efficient brushless direct current (''BLDC'') fan motors that are used in other products. In chapter 5 of the technical support document (''TSD'') that accompanied the April 2023 Direct Final Rule (''2023 Direct Final Rule TSD''), DOE noted that at efficiency level 1 (''EL 1''), which corresponds to the Tier 1 standards established in the April 2023 Direct Final Rule, efficiency improvements are achievable through optimizing the motor-filter relationship, typically by reducing the restriction of airflow (and therefore, the pressure drop across the filter) by increasing the filter surface area, reducing filter thickness, and/or increasing air inlet/outlet size.[10] These design options improve airflow across the unit, enabling the use of a smaller motor and thereby reducing power consumption. Based on a detailed examination of air cleaner models from IQAir, DOE notes that IQAir could implement these design options by altering their case design to accommodate a thinner HEPA filter, while increasing the size of the air inlet at the base of the device. These changes would allow for a reduction in the size of the motor, while maintaining a similar airflow, which would decrease the power consumption of the unit. The case design could also be improved by expanding the size of the air outlet at the top of the device, which would further improve airflow. Additionally, IQAir could change to the more efficient BLDC motor.

[10] See section 5.5.3 of the 2023 Direct Final Rule TSD for more information on technology options for improving efficiency. Available online at *www.regulations.gov/document/EERE-2021-BT-STD-0035-0024.*

IQAir expressed concern that the standards established in the April 2023 Direct Final Rule would eliminate an entire class of air cleaner products from the market. (See IQAir, No. 28 at p. 5) As discussed previously, DOE has reviewed the products using gas-filtration technology and determined that there are technology options available that would allow their products to meet the standards in the April 2023 Direct Final Rule. Given that there are technology options available for these products, DOE does not believe that this standard would cause the unavailability of air cleaner products with performance characteristics, features, sizes, capacities, or volumes that are substantially the same as those of the market at the time of the Secretary's findings. 42 U.S.C. 6295(o)(4).

Regarding cost, DOE's engineering analysis for the April 2023 Direct Final Rule considered the cost impacts of implementing the analyzed design options into air cleaners. See section 5.5.3 of the April 2023 Direct Final Rule TSD. DOE notes that EPCA does not require it to choose the standard level with the least consumer cost, or the least cost to manufacturers, but only to assess those, among other, costs and benefits (using the 7 factors articulated at 42 U.S.C. 6295(o)) and determine whether the burdens outweigh the benefits. Additionally, as discussed above, DOE has not found that this standard would result in the unavailability in air cleaners of performance characteristics, features, size, capacities, and volumes that are substantially the same as those on the market at the time of this finding. (See 42 U.S.C. 6295(o)(4)) In this case, the recommended standards met that standard, and DOE's analysis and conclusions would not change based on the comments received. Thus, DOE does not consider these comments to provide a basis to justify a withdrawal of this direct final rule under EPCA.

IQAir asserted that gas-phase air cleaners are unfairly measured by the DOE test procedure, and that their unique benefit is unrecognized. (*Id.* at p. 5) IQAir stated that the standards established in the April 2023 Direct Final Rule encompass a broad range of devices including gas-phase air cleaners, but that they are based on a measure of only particulate performance. (*Id.*) IQAir noted that the standards are based on the measurement of CADR, which describes the initial cleaning performance of a filter and is expressed with respect to specific types of pollutants (*i.e.,* $PM_{2.5}$ CADR, pollen CADR, *etc.*). (*Id.* at p. 3) IQAir noted

that while it is possible to determine CADR for gas-phase pollutants, it would still only measure initial air cleaning performance and would not account for degradation of performance over time. IQAir noted this is particularly relevant to gas-phase filtration, which relies on the capacity of granular media in order to maintain effective filtration, and without sufficient capacity, a granular filter might produce good initial gas-phase CADR and then degrade to little or no filtration. Therefore, IQAir stated, accurate measurement of gas-phase filtration must include capacity. (*Id.*)

IQAir stated that the most advanced standardized testing protocol for consumer gas-phase filtration is China's GB/T 18801–2022, titled *Air Cleaner,* which measures both initial CADR and the amount of pollutant removed from the air until CADR drops to 50 percent of the initial value. IQAir stated that this methodology effectively measures the capacity of granular filters, enabling regulators and consumers to ensure that manufacturers do not game the system by achieving high CADR or high energy efficiency with unacceptable filter life. (*Id.*) IQAir suggested DOE include means of measuring gas-phase performance and capacity, and add a proportionate allowance in the calculation of IEF, which would recognize the value of gas-phase filtration and the practicality of implementing this technology without reducing the effectiveness of the air cleaner standards on non-gas-phase air cleaners. (*Id.* at p. 6)

The Joint Stakeholders commented that it reviewed comments on the docket and observed a comment that suggested that certain products may have difficulty meeting the standards because the test procedure does not accurately measure the efficiency of the product. The Joint Stakeholders suggested test procedure waivers as a viable pathway for such products. (Joint Stakeholders, No. 31 at p. 2)

As these comments pertain to the test procedure and not the establishment of standards, DOE does not consider these comments to provide a basis to justify a withdrawal of this direct final rule under EPCA. DOE finalized its test procedure for Air Cleaners on March 06, 2023, noting that the air cleaner test procedure at appendix FF measures the $PM_{2.5}$ CADR and power consumption of air cleaners using an established industry standard, AHAM AC–7–2022. 88 FR 14014. DOE will consider any comments pertaining to test procedures, including comments suggesting additional tests for evaluating gas-filtration of air cleaners, in a future air cleaner test procedure rulemaking. In response to the comments from Joint Stakeholders, DOE notes that any interested person may submit a petition for test procedure waiver upon the grounds that the basic model contains one or more design characteristics which either prevent testing of the basic model according to the prescribed test procedures or cause the prescribed test procedures to evaluate the basic model in a manner so unrepresentative of its true energy and/or water consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(a)(1)).

D. Automatic Mode

SENSIRON AG commented that there is significant potential for energy savings by using air quality sensors for controlling the level of operation of the air cleaner, depending on the level of pollution in the indoor space where the device is used. SENSIRON AG requested that DOE consider the adoption of air quality sensors for operation control. SENSIRON AG also commented that to ensure sensors of appropriate quality are used, DOE should utilize sensor performance requirements as defined in existing healthy building standards (such as WELL [11] and RESET [12]). (SENSIRON AG, No. 27 at p. 1)

DOE addressed public comments received regarding the use of automatic mode in the air cleaner test procedure final rule published March 6, 2023 (''March 2023 TP Final Rule''). 88 FR 14014, 14032. DOE noted in the March 2023 TP Final Rule that industry-accepted test methods for other modes, such as automatic mode or low speed mode, do not currently exist. *Id.* at 88 FR 14032. As discussed in section 5.5.1.7 of the 2023 Direct Final Rule TSD, operation of air cleaners in automatic mode is not currently tested and, therefore, DOE determined that air quality sensors to improve automatic mode efficiency would not impact the efficiency levels analyzed for the direct final rule.

While SENSIRON AG included recommended standards, DOE notes that these standards are applicable to the sensors that monitor air quality, not to the air cleaner itself. As this comment pertains to the test procedure and not the establishment of standards, DOE does not consider this comment to provide a basis to justify a withdrawal of this direct final rule under EPCA. DOE is participating in the AHAM task force that is currently developing a test method for testing air cleaners with automatic mode. As stated previously, DOE would consider any updates to the test procedure in a future test procedure rulemaking.

[11] *www.wellcertified.com/.*

[12] *www.reset.build/.*

IV. Impact of Any Lessening of Competition

EPCA directs DOE to consider any lessening of competition that is likely to result from new or amended standards. (42 U.S.C. 6295 (p)(4)(A)(i) and (C)(i)(II); 42 U.S.C. 6295(o)(2)(B)(i)(V)) It also directs the Attorney General of the United States (''Attorney General'') to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(i)(V) and (B)(ii)) To assist the Attorney General in making this determination, DOE provided the Department of Justice (''DOJ'') with copies of the April 2023 Direct Final Rule, the corresponding NOPR, and the 2023 Direct Final Rule TSD for review. DOE has published DOJ's comments at the end of this document.

In its letter responding to DOE, DOJ concluded that based on its review, it does not have an evidentiary basis to conclude that the proposed energy conservation standards for air cleaners are likely to substantially lessen competition. Although the rule may limit consumers' ability to purchase non-compliant products, DOJ stated that those impacts appear to result from the rule, itself. DOJ also stated that it is not aware of likely impacts on competition or the competitive process for air cleaners that will continue to be offered. DOJ acknowledged comments expressing concerns regarding whether the proposed standard is appropriate for certain products that may have functionality beyond air cleaning (*e.g.,* vacuums) or provide air cleaning functionality that requires additional energy consumption (*e.g.,* gas phase air cleaners). DOJ stated its understanding that DOE has discretion to grant waivers from a test procedure in certain circumstances (10 CFR 430.27(f)(2)). DOJ took no positions on these comments and concerns, but encouraged DOE, should it grant waivers in other product segments, to do so in a manner that preserves competition.

In response to the April 2023 Direct Final Rule, an individual commented that the April 2023 Direct Final Rule would not allow a free market. (Slaughter, No. 29 at p. 1)

DOE considered any lessening of competition that would be likely to result from new or amended standards. Based on the DOJ review, DOE has determined it does not have an evidentiary basis to conclude that the April 2023 Direct Final Rule energy conservation standards for air cleaners are likely to substantially lessen competition.

V. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act of 1969 (''NEPA''), DOE had analyzed the direct final rule in accordance with NEPA and DOE's NEPA implementing regulations (10 CFR part 1021). DOE determined that the rule qualifies for categorical exclusion under 10 CFR part 1021, subpart D, appendix B5.1 because it is a rulemaking that establishes energy conservation standards for consumer products or industrial equipment, none of the exceptions identified in B5.1(b) apply, no extraordinary circumstances exist that require further environmental analysis, and it meets the requirements for application of a categorical exclusion. *See* 10 CFR 1021.410. Therefore, DOE determined that promulgation of the direct final rule is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA, and does not require an environmental assessment or an environmental impact statement.

VI. Conclusion

In summary, based on the previous discussion, DOE has determined that the comments received in response to the direct final rule for new energy conservation standards for air cleaners do not provide a reasonable basis for withdrawal of the direct final rule. As a result, the energy conservation standards set forth in the direct final rule became effective on August 9, 2023. Compliance with these standards is required on and after December 31, 2023.

Signing Authority

This document of the Department of Energy was signed on August 28, 2023, by Francisco Alejandro Moreno, Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 28, 2023.

Treena V. Garrett,

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

Appendix

August 9, 2023

Ami Grace-Tardy
Assistant General Counsel for
Legislation, Regulation and Energy Efficiency
U.S. Department of Energy
Washington, DC 20585
Ami.Grace-Tardy@hq.doe.gov

Re: Energy Conservation Standards for Air Cleaners, DOE Docket No. EERE–2021–BT–STD–0035

Dear Assistant General Counsel Grace-Tardy:

I am responding to your June 16, 2023 letter seeking the views of the Attorney General about the potential impact on competition of proposed energy conservation standards for air cleaners.

Your request was submitted under Section 325(o)(2)(B)(i)(V) of the Energy Policy and Conservation Act, as amended (EPCA), 42 U.S.C. 6295(o)(2)(B)(i)(V), which requires the Attorney General to determine the impact of any lessening of competition likely to result from proposed energy conservation standards. The Attorney General's responsibility for responding to requests from other departments about the effect of a program on competition has been delegated to the Assistant Attorney General for the Antitrust Division in 28 CFR 0.40(g). The Assistant Attorney General for the Antitrust Division has authorized me, as the Policy Director for the Antitrust Division, to provide the Antitrust Division's views regarding the potential impact on competition of proposed energy conservation standards on his behalf.

In conducting its analysis, the Antitrust Division examines whether a proposed standard may lessen competition, for example, by substantially limiting consumer choice, by placing certain manufacturers at an unjustified competitive disadvantage, or by inducing avoidable inefficiencies in production or distribution of particular products. A lessening of competition could result in higher prices to manufacturers and consumers.

We have reviewed the proposed standard contained in the direct final rule (88 FR 21752, April 11, 2023), the companion notice of proposed rulemaking (88 FR 21512, April 11, 2023), and the related technical support document. We have also reviewed public comments and information provided by industry participants. No Public Meeting was held in relation to this direct final rule.

Based on this review, we do not have an evidentiary basis to conclude that the proposed energy conservation standards for air cleaners are likely to substantially lessen competition. Although the rule may limit consumers' ability to purchase non-compliant products, those impacts appear to result from the rule, itself. We are not aware of likely impacts on competition or the competitive process for air cleaners that will continue to be offered.

We are aware of comments expressing concerns regarding whether the proposed standard is appropriate for certain products that may have functionality beyond air cleaning (*e.g.,* vacuums) or provide air cleaning functionality that requires additional energy consumption (*e.g.,* gas phase air cleaners). We understand that the Department of Energy (DOE) has discretion to grant waivers from a test procedure in certain circumstances (10 CFR 430.27(f)(2)). We take no positions on these comments and concerns, but encourage DOE should it grant waivers in other product segments to do so in a manner that preserves competition.

We ask that the DOE take these concerns into account in determining its final energy conservation standards for air cleaners.

Sincerely,

David G.B. Lawrence,

Policy Director.

[FR Doc. 2023–18860 Filed 8–30–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1814; Project Identifier AD–2023–00773–T; Amendment 39–22541; AD 2023–17–14]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–18–11, which applied to all The Boeing Company Model 777 airplanes. AD 2022–18–11 required repetitive inspections for cracking of the left- and right-side ring chords, repair angles, front spar lower chords, and front spar webs (depending on configuration) common to a certain underwing longeron; modification of the front spar lower chord for some airplanes; repetitive post-modification inspections; and applicable on-condition actions. This AD was prompted by a report of a crack found in a front spar lower chord, and the determination that errors in the service information mandated by AD 2022–18–11 introduced a new unsafe condition related to the application of

certain fastener cap seals. This AD retains the actions required by AD 2022–18–11, and requires a maintenance records review of previously modified airplanes for the procedures used during that modification, and applicable corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 15, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 31, 2022 (87 FR 58259, September 26, 2022).

The FAA must receive comments on this AD by October 16, 2023.

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* by searching for and locating Docket No. FAA–2023–1814; 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 final rule, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Kevin Nguyen, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3555; email: *Kevin.Nguyen@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued AD 2022–18–11, Amendment 39–22162 (87 FR 58259, September 26, 2022) (AD 2022–18–11), for all The Boeing Company Model 777 airplanes. AD 2022–18–11 required repetitive inspections for cracking of the left- and right-side ring chords, repair angles, front spar lower chords, and front spar webs (depending on configuration) common to the underwing longeron located at station (STA) 1035; modification of the front spar lower chord for some airplanes; repetitive post-modification inspections; and applicable on-condition actions. AD 2022–18–11 was prompted by a report of a crack found in the front spar lower chord of a Model 777–300ER airplane undergoing an underwing longeron replacement. The FAA issued AD 2022–18–11 to address, detect, and correct such cracking, which in combination with cracking in the front spar web, could result in a fuel leak and fire hazard, or in the case of more severe cracking, could also affect the structural integrity of the airplane.

Actions Since AD 2022–18–11 Was Issued

Since the FAA issued AD 2022–18–11, the manufacturer has discovered that Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, which was mandated by AD 2022–18–11, contains errors relating to the application of cap seals to fasteners penetrating the center wing fuel tank which introduce a second, urgent unsafe condition. These errors necessitate superseding AD 2022–18–11 to add additional actions to correct this new unsafe condition.

Fastener cap seals interior to the airplane's fuel tanks are a critical lightning protection feature. This is particularly true for the center wing fuel tank, which typically contains flammable fuel vapors more frequently than the main wing fuel tanks. As part of the front spar lower chord and underwing longeron work described in the manufacturer's requirements bulletin and mandated by AD 2022–18–11, many cap seals are removed to accomplish the various modifications and inspections. If these seals are not replaced properly, and the associated fastener has poor electrical bonding to the airplane structure for any reason, the fastener may spark during a lightning strike and cause a fuel tank explosion.

The lack of fault-tolerance introduced by these cap sealing errors in the manufacturer's requirements bulletin places an airplane with compromised cap seals that has no flammability reduction or ignition mitigation means at a level of risk that requires urgent action to address. Airplanes equipped with flammability reduction or ignition mitigation means are also affected by this newly created unsafe condition, but at a lower level of risk. Paragraph (e) of this AD, Unsafe Condition, has been revised to reflect the second unsafe condition created by the errors in the manufacturer's requirements bulletin as described above. Paragraph (e) of this AD has also been revised to reflect the determination that existing structural inspections are expected to detect severe front spar lower chord cracking before the structural integrity of the airplane is put at risk, but are not expected to detect cracking before a possible fuel leak. The unsafe condition therefore now consists of two distinct aspects: structural cracking of the front spar lower chord leading to a fuel leak and possible fire, and failure of fastener cap seals to contain a possible spark following a lightning strike leading to a possible fuel tank explosion.

The manufacturer submitted an initial report of errors in the requirements bulletin affecting cap sealing instructions in late 2022. However, given the length and complexity of the requirements bulletin, detailed and complete documentation of these errors was not received until late July 2023. The manufacturer has stated its intent to revise the requirements bulletin; however, this work will take longer to accomplish than the risk to public safety allows. Therefore, the FAA has proceeded with this supersedure without additional service information as soon as possible following the manufacturer's delivery of the necessary information. The three categories of errors affecting cap sealing instructions in the manufacturer's requirements bulletin are described as follows.

First, certain groups and configurations of airplanes have no requirement to apply cap seals to fasteners associated with the underwing longeron. Without this requirement, a cap seal may fail to be applied following modification of the underwing longeron, compromising the required fault tolerance of the fuel tank lightning protection design. For those airplanes, this AD requires application of a cap seal of the correct sealant type to the minimum thickness or greater, if not already done.

Second, certain other groups and configurations have no thickness requirement for the applied cap seal, and the requirements bulletin mistakenly refers to the Boeing Standard Overhaul Practices Manual (SOPM) section 20–50–19 for procedures to apply the cap seal. The SOPM procedure specifies a thickness that is half the necessary thickness, while the Boeing Model 777 aircraft maintenance manual (AMM) procedure, which is also referred to in the requirements bulletin, specifies the correct thickness for cap seals. It is also possible that operators may have used an accepted method other than that specified in the SOPM and AMM, as no specific procedure was required by the requirements bulletin. A cap seal of insufficient thickness may fail to contain a spark resulting from a lightning strike, similarly compromising

the fault tolerance of the fuel tank lightning protection. This AD specifies the minimum thickness and sealant type for an applied cap seal, and requires replacement of any seal that was previously applied using a procedure that specifies an inadequate thickness.

Third, some structural inspections described by the requirements bulletin may require the removal of certain fastener cap seals; however, the requirements bulletin either does not require that the cap seal be replaced, or does not provide a thickness requirement for the replaced seal. These errors affect the fuel tank lightning protection for the same reasons as already described. This AD requires that any seal removed for the inspections required by the requirements bulletin be replaced with a cap seal of correct sealant type and adequate thickness.

Therefore, for airplanes on which the actions of the requirements bulletin have not yet been accomplished, and for airplanes for which this AD requires rework of already applied cap seals, those cap sealing differences are defined in paragraph (h) of this AD as exceptions to the requirements bulletin. For airplanes on which the actions of the requirements bulletin have been accomplished but a maintenance records check cannot conclusively determine that an appropriate procedure was used to apply the cap seals, paragraph (i) of this AD requires rework of the applied cap seals.

This AD also corrects and clarifies other aspects of AD 2022–18–11 as follows.

Following the publication of AD 2022–18–11, the FAA and manufacturer discovered that Model 777–200 airplanes that do not have a fuel tank in the area affected by the unsafe condition were erroneously included in the applicability of AD 2022–18–11. As the design of these airplanes does not allow fuel to be present in the affected area (between the side-of-body ribs), the unsafe condition is not present on these airplanes. These airplanes are now identified in this AD by their maximum taxi weight of 547,000 pounds or less. Model 777–200 airplanes greater than 547,000 pounds maximum taxi weight, commonly referred to as ''777–200ERs'' (extended range), remain affected by the unsafe condition. Since the issuance of AD 2022–18–11, the manufacturer has also implemented a design change in production to address the unsafe condition. As a result, the unsafe condition does not exist on Model 777F airplanes having manufacturer line numbers 1743 and subsequent. Paragraph (c) of this AD, Applicability, has been revised accordingly.

In addition, the effectivity of the manufacturer's requirements bulletin also has the potential to cause confusion regarding the required actions for certain Model 777F airplanes. These airplanes, Model 777Fs having line numbers 1713, 1717, 1720, and 1724 through 1742 inclusive were not included in the effectivity of the requirements bulletin. While these airplanes were included in the applicability of AD 2022–18–11 and remain included in the applicability of this AD, the specific instructions applicable to them were not clearly identified in the requirements bulletin. Paragraph (h)(7) of this AD clarifies that Group 6 actions are the applicable actions for these airplanes.

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

This AD requires Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, which the Director of the Federal Register approved for incorporation by reference as of October 31, 2022 (87 FR 58259, dated September 26, 2022). This service information 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.

AD Requirements

This AD requires accomplishing the actions specified in the service information already described, except for any differences identified as exceptions in the regulatory text of this AD. This AD also requires reviewing the maintenance records of previously modified airplanes to determine the procedure used to apply cap seals, and applying and replacing certain cap seals using new specified thickness dimensions.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because a cap seal below the minimum thickness may fail to contain arcing at a fastener penetrating the center wing fuel tank during a lightning strike, potentially creating an ignition source within the fuel tank and leading to a fuel tank explosion. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–1814 and Project Identifier AD–2023–00773–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, 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 final rule 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 final rule.

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 AD 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 AD, 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 AD. Submissions containing CBI should be sent to Kevin Nguyen, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3555; email: *Kevin.Nguyen@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.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 291 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
Inspection(s) (retained actions from AD 2022–18–11).	44 work-hours × $85 per hour = $3,740 per inspection cycle.	$0	$3,740 per inspection cycle ...	$1,088,340 per inspection cycle.
Modification* (retained actions from AD 2022–18–11).	137 work-hours × $85 per hour = $11,645.	47,964	$59,609	$17,346,219.
Post-modification inspection(s)* (retained actions from AD 2022–18–11).	46 work-hours × $85 per hour = $3,910 per inspection cycle.	0	$3,910 per inspection cycle ...	$1,137,810 per inspection cycle.
Maintenance records review* (new action).	1 work-hour × $85 per hour = $85.	85	$85	Up to $24,735.

*Number of affected airplanes that will be required to do this action is unknown.

The FAA estimates the following costs to do any necessary cap sealing that would be required based on the results of the maintenance records review. The FAA has no way of determining the number of aircraft that might need the cap sealing:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Cap sealing	Up to 109 work-hours × $85 per hour = Up to $9,265.	$90	Up to $9,355.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will 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 this AD:

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–18–11, Amendment 39–22162 (87 FR 58259, September 26, 2022); and

■ b. Adding the following new AD:

2023–17–14 The Boeing Company: Amendment 39–22541; Docket No. FAA–2023–1814; Project Identifier AD–2023–00773–T.

(a) Effective Date

This airworthiness directive (AD) is effective September 15, 2023.

(b) Affected ADs

This AD replaces AD 2022–18–11, Amendment 39–22162 (87 FR 58259, September 26, 2022) (AD 2022–18–11).

(c) Applicability

This AD applies to all The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes, certificated in any category, excluding the airplanes identified in paragraphs (c)(1) and (2) of this AD.

(1) Boeing Model 777–200 series airplanes having a maximum taxi weight equal to or less than 547,000 pounds.

(2) Boeing Model 777F series airplanes with manufacturer line numbers of 1743 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by a report of a crack found in a front spar lower chord undergoing an underwing longeron replacement, and the determination that AD 2022–18–11 did not specify the appropriate thickness for the application of cap seals to fasteners penetrating the center wing fuel tank. The FAA is issuing this AD to detect and correct such cracking, which in combination with cracking in the front spar web, could result in a fuel leak and fire hazard. In addition, cap seals applied below the necessary thickness may fail to contain a spark resulting from a lightning strike, possibly resulting in a fuel tank explosion.

(f) Compliance

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

(g) Retained Required Actions, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2022–18–11, with no changes. Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021. Actions identified as terminating action in Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, terminate the applicable required actions of this AD, provided the terminating action is done in accordance with the Accomplishment Instructions of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 777–57A0122, dated October 8, 2021, which is referred to in Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021.

(h) Exceptions to Service Information Specifications

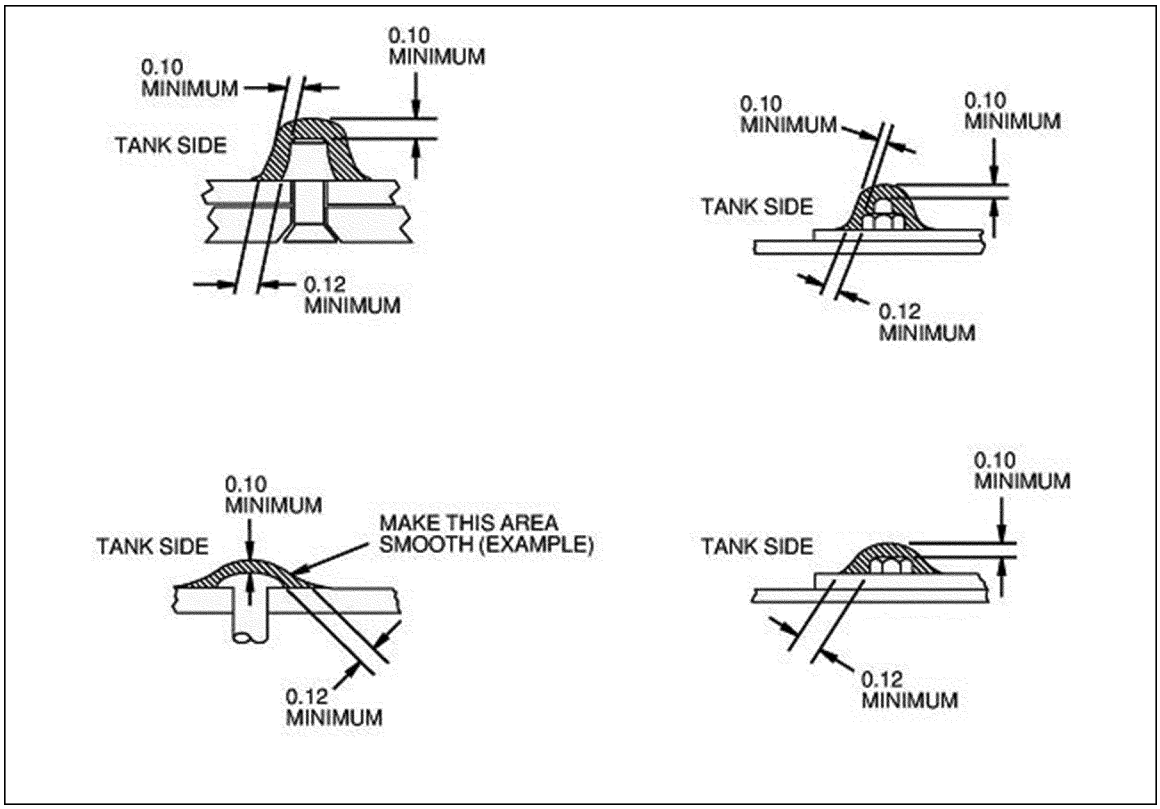
(1) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, use the phrase ''the original issue date of Requirements Bulletin 777–57A0122 RB,'' this AD requires replacing those words with ''October 31, 2022, the effective date of AD 2022–18–11.''

(2) Where Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, specifies contacting Boeing for repair instructions: This AD requires repair using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(3) Where the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, uses the phrase ''Tables 1 through 50,'' this AD requires replacing those words with ''Tables 1 through 54.''

(4) During application of any cap seal to a fastener, fastener head, and fastener threads and collars, as required by this AD, the cap seal must be applied with a thickness equal to or greater than the dimensions specified in figure 1 to paragraph (h)(4) of this AD.

Figure 1 to paragraph (h)(4)—*Cap seal minimum thickness (all dimensions in inches)*



(5) Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, does not require the application of cap seals to underwing longeron fasteners, fastener heads, and fastener threads and collars for the airplane groups and configurations

identified in paragraphs (h)(5)(i) through (iv) of this AD. For those airplane groups and configurations, however, this AD requires application of a cap seal to the underwing longeron fasteners at the locations identified in Figures 81 and 144 of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, during installation of the underwing longeron.

(i) Groups 7 and 8, Configurations 5 through 8, on the left side.

(ii) Group 9, Configurations 1 and 2, on the left side.

(iii) Groups 7 and 8, Configurations 2, 6, 10, and 14, on the right side.

(iv) Group 9, Configurations 1 and 3, on the right side.

(6) Where Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, requires inspections that may require the removal of fastener cap seals, this AD requires that if the cap seal is removed, a cap seal of BMS 5–45 sealant be reapplied with a thickness equal to or greater than the dimensions specified in figure 1 to paragraph (h)(4) of this AD before further flight after completion of the inspection.

(7) The Effectivity of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, does not include Boeing Model 777F series airplanes having line numbers 1713, 1717, 1720, and 1724 through 1742 inclusive. However, for those airplanes, this AD requires accomplishment of the applicable actions specified in the Boeing Alert Requirements Bulletin for Group 6.

(i) Actions for Previously Modified Airplanes

For airplanes on which the applicable actions of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, have been accomplished before the effective date of this AD: Within 30 days after the effective date of this AD, review the maintenance records to determine the procedures used to apply cap seals during accomplishment of the actions in Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021.

(1) If all of the conditions specified in paragraphs (i)(1)(i) through (iii) of this AD are met, no further work is required by paragraph (i) of this AD.

(i) If the underwing longeron was removed for any reason during accomplishment of the actions in Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, a cap seal was applied to the underwing longeron fasteners, fastener threads, and fastener collars at the locations identified in Figures 81 and 144 of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, during installation.

(ii) All cap seals were applied using procedures with thickness dimensions greater than or equal to those given in figure 1 to paragraph (h)(4) of this AD.

(iii) All cap seals that were removed to accomplish any inspection in accordance with Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, were replaced with cap seals of BMS 5–45 sealant of thickness dimensions greater than or equal to those given in figure 1 to paragraph (h)(4) of this AD.

(2) If any cap seal was applied using procedures with thickness dimensions less than those given in figure 1 to paragraph (h)(4) of this AD, or if the maintenance records do not definitively specify the procedures used: At the applicable time specified in paragraph (i)(2)(i) or (ii) of this AD, replace the cap seal in accordance with the Accomplishment Instructions of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, using a cap sealing procedure with thickness greater than or equal to the dimensions given in figure 1 to paragraph (h)(4) of this AD.

(i) For airplanes equipped with a flammability reduction means approved by the FAA as compliant with the fuel tank flammability reduction (FTFR) requirements of 14 CFR 25.981(b) or 26.33(c)(1), or an ignition mitigation means approved by the FAA as compliant with the FTFR requirements of 14 CFR 25.981(c) or 26.33(c)(2): Within 180 days after the effective date of this AD,

(ii) For airplanes not described in paragraph (i)(2)(i) of this AD: Within 90 days after the effective date of this AD.

(3) For any cap seal that was not applied, or for any cap seal that was removed for inspections and not replaced, or if the maintenance records do not definitively specify the procedures used: At the applicable time specified in paragraph (i)(3)(i) or (ii) of this AD, apply a cap seal of BMS 5–45 sealant using an accepted method with thickness greater than or equal to the dimensions given in figure 1 to paragraph (h)(4) of this AD.

Note 2 to paragraph (i)(3): Guidance for applying a cap seal can be found in the Boeing Model 777 Aircraft Maintenance Manual section 28–11–00.

(i) For airplanes equipped with a flammability reduction means approved by the FAA as compliant with the fuel tank flammability reduction (FTFR) requirements of 14 CFR 25.981(b) or 26.33(c)(1), or an ignition mitigation means approved by the FAA as compliant with the FTFR requirements of 14 CFR 25.981(c) or 26.33(c)(2): Within 180 days after the effective date of this AD.

(ii) For airplanes not described in paragraph (i)(3)(i) of this AD: Within 90 days after the effective date of this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety 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 certification office, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved for AD 2022–18–11 are approved as AMOCs for the corresponding provisions of Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021, that are required by paragraph (g) of this AD.

(k) Related Information

For more information about this AD, contact Kevin Nguyen, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3555; email: *Kevin.Nguyen@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.

(3) The following service information was approved for IBR on October 31, 2022 (87 FR 58259, dated September 26, 2022).

(i) Boeing Alert Requirements Bulletin 777–57A0122 RB, dated October 8, 2021.

(ii) [Reserved]

(4) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *myboeingfleet.com.*

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

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on August 28, 2023.

Victor Wicklund,

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

[FR Doc. 2023–18835 Filed 8–28–23; 4:15 pm]

BILLING CODE 4910–13–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

15 CFR Part 2004

RIN 0350–AA13

Technical Amendment: Freedom of Information Act Policies and Procedures

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Adoption of interim rule as final.

SUMMARY: This final rule adopts, without change, an interim final rule with a request for comments published in the **Federal Register** on July 25, 2023, that made a minor technical change to the USTR Freedom of Information Act (FOIA) regulation.

DATES: Effective October 2, 2023.

FOR FURTHER INFORMATION CONTACT: Janice Kaye or Monique Ricker at *FOIA@ustr.eop.gov* or 202–395–3150.

SUPPLEMENTARY INFORMATION:

I. Technical Change

On July 25, 2023, USTR published an interim final rule that made a technical change to § 2004.6 of the USTR FOIA regulation to align it with the statute and Office of Information Policy guidance about the compelling circumstances under which an agency must grant expedited processing. *See* 88 FR 47772. Although the interim final rule was effective upon publication, USTR provided a 30-day comment period, which ended on August 24, 2023. USTR did not receive any comments and is adopting the interim final rule without any changes.

II. Regulatory Flexibility Act

USTR considered the impact of this rule and determined that it will not have a significant economic impact on a substantial number of small business entities because it applies only to USTR's internal operations and legal obligations. 5 U.S.C. 605(b).

III. Paperwork Reduction Act

The final rule does not contain any information collection requirement that requires the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

IV. Administrative Procedure Act (APA)

On July 25, 2023, USTR published an interim final rule (88 FR 47772) and determined that there was a basis under the Administrative Procedure Act for issuing the interim final rule with immediate effect. USTR provided a 30-day comment period, which ended on August 24, 2023. USTR did not receive any comments and is adopting the provisions of the interim final rule as a final rule with no changes.

List of Subjects in 15 CFR Part 2004

Administrative practice and procedure, Courts, Disclosure, Exemptions, Freedom of information, Government employees, Privacy, Records, Subpoenas, Testimony.

PART 2004—DISCLOSURE OF RECORDS AND INFORMATION

■ Accordingly, the interim final rule published in the **Federal Register** on July 25, 2023, at 88 FR 47772, amending 15 CFR part 2004, is adopted as a final rule without change.

Janice Kaye,

Chief FOIA Officer, Office of the United States Trade Representative.

[FR Doc. 2023–18866 Filed 8–30–23; 8:45 am]

BILLING CODE 3290–F3–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1303 and 1315

[Docket No. DEA–455]

RIN 1117–AB49

Management of Quotas for Controlled Substances and List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is publishing this final rule to manage the quotas for controlled substances and the list I chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine, held by DEA-registered manufacturers. This final rule will define the types of quotas, update the method to abandon quota, clarify the current language to ensure that both manufacturers and distributors are required to obtain certification of a buyer's quota, reduce overall inventories, formalize the existing practice of use-specific subcategories for individual manufacturing and procurement quotas, and modify existing deadlines to fix/issue quotas. This final rule will also amend certain regulations to implement updates to the Controlled Substances Act made by the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act.

DATES: This final rule is effective November 29, 2023.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting & Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) authorizes the Administrator of the Drug Enforcement Administration (DEA) (by delegation from the Attorney General) to promulgate rules and regulations that he deems necessary and appropriate for the efficient execution of his functions under subchapter I (Control and Enforcement) and subchapter II (Import and Export). 21 U.S.C. 871(b) and 958(f). Subchapter I includes provisions which require the Administrator to establish the aggregate production quota for each basic class of controlled substance listed in schedules I and II and the assessment of annual needs for the ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in the United States each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. 21 U.S.C. 826. The Administrator shall take the following quota actions for a basic class of controlled substance listed in schedules I and II and ephedrine, pseudoephedrine, and phenylpropanolamine pursuant to stipulated conditions: limit or reduce individual production quotas for each registered manufacturer,[1] and fix individual manufacturing quotas for registrants.[2]

On October 24, 2018, Congress revised the CSA through the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities (SUPPORT) Act. These revisions will be noted and included in these proposed regulations, where applicable. Through this Act, the Administrator, by way of delegation from the Attorney General, may now set quota in terms of the pharmaceutical dosage-form.

[1] 21 U.S.C. 826(b).

[2] 21 U.S.C. 826(d).

I. Executive Summary

A. Notice of Proposed Rulemaking

DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** on October 23, 2019, which provided an opportunity for comments to be submitted. 84 FR 56712. The comment period closed on December 23, 2019. DEA invited comments from the public on all of the topics covered in the NPRM; however, DEA cannot change the implementation of amendments from the SUPPORT Act.

B. Summary of the Purposes and Provisions of the Rule

1. Types of Quota

In the NPRM, DEA proposed the addition of new sections to introduce and define the types of quotas and proposed an update to the procedure for abandoning quota. The types of quotas are as follows:

- Aggregate production quota (APQ) (for controlled substances);
- Assessment of Annual Needs (AAN) (for list I chemicals); [3]
- Individual Manufacturing Quota (for controlled substances and list I chemicals);
- Procurement Quota (for controlled substances and list I chemicals); and
- Import Quota (for list I chemicals).

Through this final rule, DEA will add these new sections to the regulations that will define the types of quotas for controlled substances in schedules I and II and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Also, DEA will change the regulations to stay up to date with modern technology by formalizing the current practice of filing to abandon quota with the United Nations (UN) Reporting and Quota Section in the online Quota Management System.

2. Conforming Changes From the Substance Use-Disorder Prevention That Promotes Opioid Recovery Treatment for Patients and Communities Act

In the NPRM, DEA introduced the SUPPORT Act [4] and informed the public of the new legislation as it applies to DEA. With this final rule, DEA is updating the current regulations to comply with this new law. The SUPPORT Act now gives the Administrator, by way of delegation from the Attorney General, the authority to establish the APQ, individual manufacturing quotas, and procurement quotas in terms of pharmaceutical dosage-form prepared from or containing a controlled substance. The SUPPORT Act also changed the deadline for DEA to fix the individual manufacturing quota for schedules I and II controlled substances. The SUPPORT Act defines the phrase ''covered controlled substance'' and mandates that the amount of diversion of a covered controlled substance be estimated when establishing any quota. When estimating diversion, DEA must consult with the Department of Health and Human Services (HHS) on rates of overdose deaths, rates of abuse, and the impacts on overall public health related to the covered controlled substances. DEA may also take into consideration other sources of information deemed reliable. The SUPPORT Act requires that ''appropriate quota reductions'' be made after estimating diversion. The Act does not require quota increases.

3. Procurement Quota Certification

DEA proposed to change the regulations to require certification of procurement quota in the NPRM. This final rule changes the regulations to provide that both manufacturers and distributors selling to a manufacturer will be required to obtain certification of the buyer's quota when an order is placed. This is implemented by changing the words ''importer,'' ''manufacturer,'' and ''bulk manufacturer'' to ''registrant.''

4. Inventory Allowances

In the NPRM, DEA proposed reductions to the acceptable inventory allowance, the amount of inventory at which quota would be suspended, and when DEA would grant a request for additional quota. DEA also proposed the establishment of inventory allowances for procurement quota for controlled substances. Due to comments and concerns received from the NPRM, DEA will be implementing different provisions in this final rule. Instead of the proposed amendments, DEA will:

- Decrease the inventory allowance issued by DEA for individual manufacturing quotas from 50 percent to 40 percent;
- Establish an inventory allowance issued by DEA for all procurement quotas, except liquid injectable products, at 35 percent, instead of the proposed 30 percent;
- Establish an inventory allowance issued by DEA for liquid injectable dosage-form procurement quotas at 50 percent, instead of the proposed 30 percent;
- Suspend individual manufacturing quota issued by DEA if a registrant's inventory exceeds 55 percent (reduced from 65 percent) of the registrant's estimated net disposal;
- Suspend procurement quota issued by DEA, except that for liquid injectable dosage-forms, if a registrant's inventory exceeds 50 percent of the registrant's estimated net disposal;
- Suspend liquid injectable dosage-form procurement quota issued by DEA if a registrant's inventory exceeds 65 percent of the registrant's estimated net disposal;
- Review request to determine if request for additional individual manufacturing quota by registrant should be granted when inventory is less than 30 percent (reduced from 40 percent) of the registrant's estimated net disposal;
- Review request to determine if request for additional procurement quota, except for liquid injectable dosage-forms, by registrant should be granted when inventory is less than 25 percent of the registrant's estimated net disposal;

and

- Review for request to determine if request for additional procurement quota for liquid injectable dosage-forms by registrant should be granted when inventory is less than 40 percent of the registrant's estimated net disposal.

5. Subcategories for Quotas

DEA proposed the addition of use-specific subcategories for individual manufacturing and procurement quotas to formalize the current, on-going practice of the use of these subcategories by registrants. The use-specific subcategories are:

- Quota for Commercial Sales;
- Quota for Transfer;
- Quota for Product Development;
- Quota for Replacement; and
- Quota for Packaging/Repackaging and Labeling/Relabeling.

6. New Deadlines To Establish Quotas

In the NPRM, DEA proposed changes to the deadlines for fixing or establishing the different types of quotas to allow more time for processing and communicating with applicants and to make the regulations consistent with the SUPPORT Act. This final rule will implement the following new deadlines:

- Deadline to establish the APQ and the AAN: change to September 1;
- Deadline to issue individual procurement, import, and manufacturing quotas: change to December 1; and
- Deadline to adjust individual manufacturing quota: change to July 1.

[3] For the purposes of this document only, ''list I chemicals'' refers to ephedrine, pseudoephedrine, and phenylpropanolamine for legitimate medical, scientific, research, and industrial needs. The phrase ''list I chemical(s)'' will be used going forward.

[4] The SUPPORT for Patients and Communities Act, Public Law 115–271.

II. Discussion of Comments

DEA received 258 comments. Many comments addressed multiple topics of the NPRM. Commenters also addressed the changes made to the CSA by the SUPPORT Act, which Congress put into effect.

A. Defining Types of Quota and Filing To Abandon Quota

Issue: DEA received nine comments regarding the definitions and types of quotas and three comments regarding the updates for the process of abandoning quota. Comments received from several organizations stated that they support DEA's changes to its regulations introducing and defining the types of quota. One company justified its support stating that DEA's change serves to educate and inform those not familiar with the quota process.

While one pharmaceutical company had no objections to the definitions of the types of quotas, they stated that DEA should consider creating a distinct sixth type of quota: procurement quota utilized to import concentrate of poppy straw (CPS) or raw opium that should remain independent of any inventory restraints. This company further suggested that the 30 percent inventory range would be too restrictive and would risk supply disruption from one year to the next as it believes a higher inventory range is necessary both to create a buffer in the first quarter of a new year and to avoid disruption in the event of delivery delays involving United States Customs and Border Protection.

Many commenters also fully supported the formalization of the quota abandonments with the UN Reporting and Quota Section in the online Quota Management System. One commenter explained its support by stating that these changes will allow for automation of the abandonment/surrender process. One pharmaceutical company recommended DEA take advantage of the opportunity provided by modifying the quota regulations to include the same provision in the section for procurement quota. This same company believes this will better reflect current practice as both manufacturing and procurement quota utilize the same mechanism for surrendering unnecessary quota.

DEA Response: DEA is committed to taking into consideration any changes in market dynamics that may require allocation of individual manufacturer's quotas or revisions to the APQ. DEA is also committed to ensuring that quotas are set in a way as to grant manufacturers the ability to provide controlled substances to meet the demands of the legitimate medical, scientific, and export needs of the United States. It has been DEA's long-standing intent to improve the process of setting the annual quota while ensuring an adequate supply of controlled substances is available for legitimate needs.

A sixth category of procurement quota for the acquisition of CPS or raw opium imported in compliance with DEA regulations for the purpose of removing restraints on inventory allowances whose aims are to ensure availability is unnecessary. First, there are a very small number of entities (<10) registered in the United States to procure narcotic raw materials (NRMs) for processing into schedule II controlled substances and these companies have a long history of obtaining the NRM necessary to meeting the estimated needs of the United States.

In addition, there are inventory allowances built into multiple quotas that DEA grants to those who produce active pharmaceutical ingredients (APIs) derived from NRM. Prior to implementing this rule, DEA granted a 50 percent inventory allowance to registered bulk manufacturers that procure NRM for the API they produce each year, pursuant to a DEA issued manufacturing quota. That total quantity (*i.e.,* 150 percent of estimated net disposals minus any existing inventory on hand) is then utilized to calculate the amount of procurement quota that the bulk manufacturer requires to make the API for which a manufacturing quota was granted. In those instances, DEA assesses the amount of NRM necessary to produce the above-mentioned API and then calculates an inventory allowance on the amount of NRM required. Both inventory allowances ensure that there are adequate amounts in the drug supply to meet legitimate needs. Finally, while appropriate safeguards are currently in place, the potential for diversion still exists for NRM from excessive stockpiling of NRM due to changes in legitimate need of the end products which may reduce the need to manufacture.

In addition, DEA appreciates the comments received in support of the process to formalize quota abandonments. Formalizing the procedure to abandon quota is simply a codification of existing DEA practice. While this formalization will have no economic costs or benefits, DEA believes there are benefits to accurately codifying existing practices. As such, this final rule will enhance efficiency and improve the process to abandon the right to manufacture all or any part of both individual manufacturing and procurement quotas.

B. Conforming Changes From the SUPPORT for Communities and Patients Act

DEA received nine comments about the changes imposed by the SUPPORT Act. As stated in the NPRM, these updates to DEA's regulations are being implemented to comply with the amendments made to the CSA by the SUPPORT Act. While DEA does not have the authority to change what has been established by Congress, DEA will still discuss the comments below.

The Establishment of Quotas in Terms of Pharmaceutical Dosage-Forms

Issue: By way of the SUPPORT Act, DEA's regulations were changed to allow quotas to be established in terms of pharmaceutical dosage-forms. In the NPRM, DEA explained that the discretionary authority granted to DEA to establish APQ, procurement, and individual manufacturing quotas in terms of pharmaceutical dosage-forms would not be used at this moment. The comments received addressed DEA's decision to delay the use of this discretionary authority, with some disagreeing with DEA's decision not to use the authority at this moment. Some suggested that DEA note the distinction between manufacturing injectables (which are given to in-patients) versus oral solid dosage-forms. These commenters opined that setting the quotas in terms of pharmaceutical dosage-forms will help address nationwide shortages of injectables.

DEA Response: In the matter of DEA's decision not to use the discretionary authority at this present time, DEA emphasizes that the SUPPORT Act states that DEA (by delegation from the Attorney General) *may* establish the quotas in terms of pharmaceutical dosage-forms prepared from or containing the controlled substance when it is determined that these such establishments will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. This is not an express requirement to grant quotas in that manner, however it does grant the authority to do so. If DEA were to exercise its discretionary authority, it would be implemented at the procurement quota level, which would have a more direct impact on the availability of specific dosage-forms for legitimate medical need. During the analysis and review process for individual procurement quotas, DEA examines in detail the supporting documentation provided by dosage-form manufacturers to distinguish the type of

product to be manufactured. This includes the type of formulation (solid, oral liquid, or liquid injectable) and dosage strengths, which become part of the factors considered in estimating an appropriate procurement quota accordingly.

Currently, all liquid injectable products receive 50 percent inventory allowance. DEA will continue issuing the inventory allowance for these dosage-forms at the same percentage because there are significantly fewer dosage-form manufacturers of injectable products. DEA is aware that quality or production problems related to sterility issues for injectable products have led to higher likelihood of recalls of such products. DEA believes that these products, when administered in controlled clinical and hospital settings, decrease the likelihood of diversion due to higher levels of oversight. Furthermore, the ongoing Coronavirus Disease of 2019 (COVID–19) public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, has made it necessary for DEA to consider both the potential for diversion, as well as the anticipated increase in demand for injectable products used to treat patients suffering from COVID–19. Due to COVID–19, DEA had to issue an adjustment to the established APQ for 2020 [5] for selected controlled substances involved in manufacturing injectable drug products for COVID–19 treatment. The adjustment of APQ allowed DEA to adjust the individual procurement quotas and related inventory allowances for injectable products. While DEA declines to establish APQ in terms of pharmaceutical dosage-forms at this time, DEA has decided to implement a separate inventory allowance for liquid injectable dosage-forms. This will be discussed later in the document.

Deadline To Fix Individual Manufacturing Quotas

Issue: DEA also received a comment from an individual regarding the date change for fixing the individual manufacturing quota. The commenter asked, ''how and why did DEA have Congress change the date to December?''

DEA Response: The SUPPORT Act revised the CSA by issuing a mandatory change to the date by which DEA must fix individual manufacturing quotas to ''on or before December 1.'' Because Congress issued this change, DEA must follow this law and implement the new date into DEA's regulations.

Estimation of Diversion

Issue: DEA received comments that were in support of DEA providing explanations for the increase in quotas but there was concern with the reliability of the data available for abuse (manufactured products vs. illicit substances). Commenters suggested DEA consider a broader range of data when calculating diversion by considering sources that are already available, pushing for even better data sources for future years, and adopting a uniform method of accounting for diversion. They stated that DEA should exhaust other means of curtailing illegitimate sales, abuse, and diversion before looking to quota as a prevention tool. Companies suggested that DEA differentiate among specific dosage-forms and target the dosage-forms that are subject to abuse to encourage the use of dosage-forms that are less prone to diversion. They stated that there needs to be an objective evaluation considering the exclusion of injectable dosage-forms from quota reductions. Commenters also suggested that DEA account for over-prescribing as a part of the diversion analysis by considering data and best practices of healthcare providers and by collecting information from the Prescription Drug Takeback Programs and similar sources. Further, they suggested that DEA use the medical professionals' ''best practices'' to help account for overprescribing at the physician level and incorporate data collection into the Prescription Drug Takeback Program to account for overprescribing at the patient level.

DEA Response: The Food and Drug Administration (FDA) is responsible for approving drug products and can require a manufacturer to submit a Risk Evaluation and Mitigation Strategy (commonly referred to by the industry as a REMS), which is a risk management plan that uses tools beyond the prescribing information to ensure that the benefits of certain drugs outweigh their risks. Certain REMS may include strategies to prevent, monitor, and manage specific risks resulting from inappropriate diversion and abuse of products. The information provided from a REMS informs DEA of potential abuse liability issues that may lead to diversion. If a manufacturer believes that its product is potentially being diverted or abused within the supply chain based on customer orders received that raise suspicion, it is responsible for notifying DEA by sending a report to the agency through DEA's Suspicious Orders Reporting System (SORS). *See* 21 U.S.C. 802(57), 21 CFR 1301.74(b). Once notified, DEA will alert the field office regarding the situation. The diverted amount will then become a factor when processing the quota for the current year and an adjustment to the amount of quota granted will be made indicating the diverted amount. DEA also acquires data from HHS, Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and the States to determine reliable rates of overdose deaths, abuse, and overall public health impact as a factor of diversion to make appropriate quota reductions for each of the covered controlled substances. DEA conducts diversion analysis for the five covered controlled substances and the remaining drugs not considered a ''covered controlled substance'' by the SUPPORT Act.

C. Procurement Quota Certification

Issue: DEA received three comments from industry expressing concern about DEA's change to the regulations to ensure that both manufacturers and distributors selling to a manufacturer are required to obtain certification of a buyer's quota for the request of schedule I and II controlled substances, as well as list I chemicals when the buyer is a manufacturer.

One pharmaceutical company felt that the proposed changes seemed too broad. This company did not question the requirement to provide a certificate of quota when purchasing from a distributor or a manufacturer. However, the company stated that the specific wording of the proposed regulation may be overly broad. According to the company, as worded, the proposed regulation would require a certificate for orders from any registrant. The company believed this wording could be construed to apply to reference standards from analytical sites or complaint samples and certificates should not be required when manufacturers order from pharmacists, health care practitioners, or analytical laboratories.

DEA Response: By requiring that any manufacturing registrant provide a certification of quota before receiving any quantity of a schedule I or II controlled substance or list I chemical,

[5] DEA published *Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020* in the **Federal Register**, 84 FR 66014, on December 2, 2019. In response to COVID–19, DEA published *Adjustments to Aggregate Production Quotas for Certain Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine and Pseudoephedrine for 2020, in Response to the Coronavirus Disease 2019 Public Health Emergency* in the **Federal Register**, 85 FR on April 10, 2020, to address any potential shortages that may occur during the public health emergency.

DEA is better able to maintain the closed distribution system and provide a more accurate calculation of the APQ for the United States per 21 CFR 1303.12(f). While DEA is not averse to manufacturers fulfilling legitimate medical needs, DEA is required to ensure that enough quota is granted to meet legitimate medical, scientific, and research needs, while preventing diversion. To prevent diversion and to maintain a closed distribution system for schedule I and II controlled substances and list I chemicals, DEA requires any registrant to whom a procurement quota has been issued to follow the laws and regulations of the CSA and Code of Federal Regulations (CFR). One method of doing this is to require all registrants sending material to a manufacturer to verify proof of quota through certification, which ensures that purchases do not exceed the procurement quota set by DEA.

D. Inventory Allowances

There were 23 in-scope comments that discussed the proposed reductions of inventory allowances. Many of the comments discussed each reduction separately. Furthermore, many of the comments from companies asked DEA to clarify which registrants the various reductions would be applicable to, due to the current placement of the regulations in the CFR. In general, commenters objected because of the economic impact to their business and the inability to ensure adequate supply. Commenters contend that DEA should not use a one-size fits all method for inventory and limiting additional quota because it will create a constant state of backorder and market shortage. A commenter proposed a grace period of at least one year before making the reductions effective.

Reduction and Establishment of New Inventory Allowances for Individual Manufacturing Quotas and Procurement Quotas From 50 Percent to 30 Percent

Issue: Commenters objected to the reduction/establishment of inventory allowance stating that the lower amount of inventory allowance combined with the new date for individual manufacturing and procurement quotas may cause a shortage. A commenter stated that DEA's data on theft and loss at the manufacturing level show that the security of the products exceeds the security at the retail level. Commenters asked DEA to name studies showing that increased inventory at manufacturing facilities correlates to an increase in diversion or abuse. Further, many commenters allege that the proposed changes will create incentives that may increase opportunities for diversion and conveyed that DEA should assess whether reducing quotas would create shortages and jeopardize patient care. Commenters also emphasized that DEA needs to evaluate carefully the legitimate supply chain's full throughput time to bring medicines to market, so that patient care is not jeopardized.

Many commenters conveyed that the proposed 30 percent inventory allowance for procurement quota is overly restrictive and such a reduction would cause inefficiencies and shortages. Furthermore, it was commonly said that the reduction would hinder the ability to provide consistent care to patients, and it may result in potential shortages in hospitals and clinics and severely impact those patients managing an opioid dependence. They mentioned that there was already a shortage in acute care facilities.

Commenters suggested that DEA should give further consideration to the potential for supply disruptions that would result from decreasing the inventory allowance for API bulk manufacturers from 50 percent to 30 percent. It risks imposing significant costs and inefficiencies on the production of authorized bulk drug substances without corresponding benefits.

Commenters also stated that DEA's claim that the reductions will not increase the likelihood of shortages because there has been an increase in the number of manufacturers is too broad. Manufacturers of approved drug products can only use the approved suppliers that they named in their FDA-approved applications. Typically, manufacturers of approved drug products only have one or two suppliers that they can use. Commenters also said that DEA misstated data when claiming that the proposed reduction should not affect manufacturers. Three manufacturers supply over 90 percent of the API for codeine, hydrocodone, oxycodone, and morphine; therefore, there are fewer API producers in 2019 than 2007. API from one of the three primary manufacturers is not interchangeable across dosage-form manufacturers without FDA approval. In respect to procurement quotas, commenters alleged that the reduction to 30 percent would leave no margin for recovery. They also stated that the reduction to 30 percent will result in unnecessary restraints on API manufacturers.

Multiple commenters want DEA to keep the existing allowances of 50 percent for bulk manufacturers and state DEA should consider possible alternatives to reduce the additional cost burdens and risks of shortages and diversion. Commenters frequently claimed that DEA did not provide data to support its claim that the reduction for individual manufacturing quota inventory allowances would reduce the potential for diversion, especially because commenters believe that the material is not desirable at the bulk manufacturing level. They also mentioned that the reductions will substantially increase the cost of bulk manufacturing, will increase the risk of shortages of API supplies, and may increase the risk of diversion. In respect to bulk and dosage-form manufacturers, commenters assert the reduction could be harmful to patients and will potentially lead to market shortages of injectable medicines needed for critical medical care. Commenters also alleged that constricting inventories at pharmaceutical manufacturers or in institutional settings will have little impact on curbing diversion. Many commenters conveyed the want for DEA to publicly provide data that validates and supports the need for any reductions in inventory allowances.

Commenters asked for clarification on whether the 30 percent inventory allowance would be applicable to dosage-form manufacturers, due to its placement in the CFR. They suggested that if DEA applies the inventory allowance to dosage-form manufacturers, then it only be reduced for domestic consumption and not for exports. They also suggested that dosage-form manufacturers be allowed to calculate their allowance using the estimate of the current year's sales and bulk manufacturers calculate their allowance using the average of the preceding calendar year and the current calendar year. Several commenters mentioned that year-end inventory is not indicative of how much inventory they require throughout the year because a manufacturer's inventories are lowest at year-end as they have sold down their stock and await the granting of quota for the next calendar year. Commenters opined that the reduction of inventory from 50 to 30 percent is counter intuitive because more quota is needed due to the additional waste that would be caused from the increased number of manufacturing campaigns that would be required. Furthermore, they alleged that DEA will experience an increase in the amount of quota requests due to this reduction.

A few commenters worried that the reductions may not have a significant effect on a provider's decision to prescribe. They explained that if DEA

limits production but providers continue to prescribe at the same rate, the issue will not have been addressed. Instead, costs may rise as supply decreases due to the reduction in production. One organization recommended that DEA pay greater attention to evidence-based research on appropriate prescribing and provide greater education for physicians and patients based on this research.

DEA Response: DEA has been working to prevent and to decrease diversion for years. DEA uses Composite Risk Management [6] to assess the risk of diversion at all levels of the supply chain. While diversion at the manufacturing level may be low, DEA emphasizes that there is still the potential for diversion to occur at that level. When setting quotas for the year, DEA assesses whether they would cause a shortage or jeopardize patient care. Also, DEA uses several sources of data to evaluate legitimate supply chains, such as Automated Reports and Consolidated Ordering System (ARCOS), IQVIA, and manufacturers' own data. The quotas granted are a composite of estimated requirements for legitimate medical, scientific, and export needs, manufacturing yields, and inventory allowance to begin to meet the next year's legitimate needs while reducing the risk of diversion.

While there may not be published studies showing that an increase in inventory at manufacturing facilities correlates to an increase in diversion or abuse, a fundamental principle governing policy discussions and DEA rulemaking, especially during the height of an opioid epidemic, is that DEA must strike a balance between ensuring an adequate and uninterrupted supply of controlled substances while preventing an oversupply which increases the risk of diversion. DEA does have internal information that it takes into consideration when granting individual quotas at that time. Review of internal actions of enforcement measures taken over the years have shown thefts at the manufacturing level and the public health impact in the surrounding communities as a result of those thefts. There have been occurrences of thefts of bulk API and thefts of finished dosage-forms from manufacturers' production facilities, and these products were sold into the community. Overproduction of API and finished dosage-forms can lead to high inventories and questionable high pressure marketing practices. DEA notes that manufacturers cannot sell more than their granted quotas plus previous year inventories but that high inventories could allow small thefts to go unnoticed from production facilities.

DEA understands the worries of commenters regarding the reduction of inventory allowances possibly jeopardizing patient care; however, DEA wants to stress that the management of patient care is not controlled by way of quotas. While DEA is aware of the opioid crisis, the issuance of quotas and accompanying inventory allowances are not directly involved with the management and care of patients. The issuance of quotas does not regulate the physician's practice of medicine. Therefore, inventory allowance reductions would not hinder a physician's ability to provide consistent care to patients, as voiced by commenters. DEA does not regulate a provider's prescription methods so long as there is a legitimate medical need. While the inventory allowance reductions apply to what manufacturers hold in inventory to begin dispositions for the next calendar year, they can utilize the inventory in the event that there is a shortage or there is an issue in the supply chain during manufacturing to prevent disruption to the legitimate supply chain. DEA does not control the way a company conducts business, as business decisions on production and supply chain management are done on the company level. DEA notes that it is HHS' area of responsibility to provide Evidence Based Medicine as guidance to providers and the public.

While there are a few commenters who have shared the concern that DEA's reduction of inventory will not have much of an effect on overprescribing, DEA believes that this is one of many factors being implemented at the federal level that will have an impact on decreasing overdoses due to prescription medications. DEA also notes that there has been a decline in the prescribing of schedule II opioid prescriptions since 2016 as many of those other factors have been implemented at Federal and state levels. As shown by IQVIA and demonstrated by a review of CMS' data, prescribing rates for opioids have decreased 44 percent since 2016 without a significant increase in price.[7]

While commenters opined that DEA is being too broad in stating that the increase in manufacturers will offset the chances of a shortage, DEA did not generalize or understate the concept of there being enough dosage-form manufacturers so as not to increase the chances of shortages. Most dosage-form companies may have one main API supplier to ensure a continuous supply of product to meet patient need and mitigate the impact of potential shortage of the product. However, many dosage-form manufacturers have named a second supplier in FDA-approved applications and can request API from either supplier to meet legitimate patient need. While a secondary supplier is not required for New Drug Application or Abbreviated New Drug Application approval, DEA has noted that most requests for product development quota include a second supplier of API. DEA reviewed FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (hereinafter ''Orange Book'') to determine the number of approved products and then matched those products to DEA registered manufacturers. In the event that there is an increase in a company's risk of shortage of supplies, the applicant may file for additional quota at any time during the calendar year. During that time, the application, along with its supporting documents, will be reviewed and if needed, an adjustment to the quota will be granted. Currently, DEA has already been applying the reduced inventory allowance of 30 percent to fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone.

DEA has decided to reduce the individual manufacturing inventory allowance for all controlled substances and list I chemicals to 40 percent and the procurement inventory allowance for controlled substances and list I chemicals to 35 percent, with the exception of liquid injectable dosage-forms. For liquid injectable dosage-forms, the procurement quota inventory allowance will be set at 50 percent. The inventory allowance requires that manufacturers maintain their inventory allowance based on estimated net disposals for the calendar year. It is based on what the manufacturer estimates their disposal to be and not the actual disposal at a specific point in time. DEA requires year-end reporting that demonstrates the manufacturer ended the year with the correct inventory allowance percentage. The inventory allowance does not affect the amount of a net-disposition quota granted to a manufacturer. DEA grants the quota necessary to be able to continue to meet legitimate patient needs based on the historical and

[6] For purposes of this document, Composite Risk Management is a decision making process used to mitigate risk associated with all hazardous equipment or impact to the mission.

[7] The Centers for Medicare & Medicaid Services, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Medicaid.html,* accessed 6/15/2020.

estimated future data including changes in market share and FDA guidance. DEA grants an inventory allowance to the manufacturer to begin disposition for the next year; however, this may also be used to meet the unanticipated market changes in the current year. API and/or finished dosage-forms in reserve are usually held for unanticipated market changes, manufacturing issues, and to begin the next year. As such, DEA's lowering of the inventory allowance as written in the regulations should not affect a manufacturer's sales. While diversion may not occur with high frequency at the manufacturing level, it occurs and can impact public health in the surrounding community. Since 2004, DEA has sought to address risk of diversion at the apex of the distribution system (*i.e.,* manufacturing level). Granting higher inventory based on sales provides more incentive to push more material further downstream as no entities want to maintain higher levels of stocks than what they deem necessary due to storage and monetary constraints, the fact is that profit is only generated through sales of the product and not production. DEA previously demonstrated that bulk manufacturers were only holding 39 percent inventory. It is for these reasons, and the fact that historically manufacturers have not held 50 percent inventory levels, that a lower inventory at the manufacturer level should be implemented. Also, the lower inventory allowances can potentially reduce diversion throughout the supply chain.

DEA notes that bulk manufacturers have not always utilized all of their granted quota to manufacture API and have consistently held less than 50 percent inventory. The year-end sales and inventory provides information on how a registrant is doing in the market and provides a starting point when assessing requests for revisions to current quotas. If a bulk manufacturer's sales to customers are more robust than anticipated, inventories will be low and DEA will grant a quota adjustment to ensure that the customers can receive material up to their individually granted procurement quota. If inventories are high, it indicates that the company has not sold as much API to their customers as they forecasted, and therefore the higher inventory allowance is unnecessary.

Over the last decade, DEA has implemented a 30 percent inventory allowance for opioid related procurement quotas. This inventory level has not caused issues due to quota being set at the legitimate patient level. DEA notes that over the last four years, after reviewing the applicants' year-end reports and other data reporting sites, dosage-form manufacturers have reported higher than average inventories of opioids as prescriptions for opioids have declined significantly due to the implementation of CDC guidelines and DEA enforcement activities. The data show that manufacturers only acquired 72.7 percent of fentanyl, 73.9 percent of hydrocodone, 56.7 percent of hydromorphone, 79.3 percent of oxycodone, and 73 percent of oxymorphone from the quotas granted to them by DEA. As prescription rates have fallen, the data show that the material has not sold, but has been moved to their inventory, thereby significantly increasing inventory levels above that which are medically necessary on an annual basis. DEA has found that over the past years, inventory levels have averaged 72 percent for fentanyl, 36.9 percent for hydrocodone, 57 percent for hydromorphone, 36.3 percent for oxycodone, and 61.0 percent for oxymorphone, while companies have met legitimate medical needs. The inventory levels for fentanyl, hydromorphone, and oxymorphone include product development efforts as manufacturers seek FDA approval of abuse-deterrent formulations. DEA has considered the comments from manufacturers and will set the inventory allowance for procurement quotas at 35 percent for all dosage-forms, except liquid injectable dosage-forms. Liquid injectable dosage-forms will receive a 50 percent inventory allowance for procurement quotas.

To determine the amount for the procurement quota inventory allowance, DEA has reviewed the Orange Book and internal quota applications. These reviews led DEA to determine that, generally, there are more dosage-form manufacturers than bulk manufacturers, and as such, an individual dosage-form manufacturer does not need as great of an inventory as a bulk manufacturer. Therefore, the procurement quota inventory allowance should be lower than the manufacturing quota inventory allowance. DEA has considered new data from FDA on new approved drug applications and internal quota applications that showed that manufacturers are producing or seeking to produce more extended-release and/or abuse-deterrent dosage-form products that require additional manufacturing time compared to immediate-release drug products. Therefore, DEA has determined that a procurement quota inventory allowance of 35 percent provides the necessary manufacturing lead time to prevent shortages or gaps in the supply chain. DEA believes this increase in inventory allowance from the proposed amount will provide the necessary time for all manufacturers to complete their manufacturing activities and place their products in the supply chain for legitimate need.

However, DEA will not be reducing the inventory allowance for procurement quotas of the liquid injectable dosage-forms. After further review of comments, DEA acknowledges that for injectable products, there are significant manufacturing issues when manufacturers fail to comply with FDA's Current Good Manufacturing Practice (cGMP) regulations. Additionally, DEA has realized that the lower number of manufacturers, coupled with the higher likelihood of recalls due to cGMP violations, requires the higher inventory allowance for dosage-form manufacturers of injectable products. In light of COVID–19, DEA also acknowledges that declining to reduce inventory allowances for these liquid injectable dosage-forms ensures that manufacturers are able to address and endure potential circumstances of nationwide shortages. The liquid injectable dosage-form procurement quotas will be set at 50 percent.

DEA read the comments regarding the limited number of bulk manufacturers supplying the market. DEA and international drug control treaty obligations control the number of bulk manufacturers who supply the dosage-form manufacturers. While the number of bulk manufacturers may fluctuate, over the past 10 years there have been 10 bulk manufacturers that have supplied the opioid market, with three of them supplying the majority of the requirements. DEA analyzed the data and determined that the bulk manufacturers did not utilize the entire quota granted to them each year. On average, the companies manufactured only 85.2 percent of the fentanyl, 61.7 percent of the hydrocodone, 79.1 percent of the hydromorphone, 78.3 percent of the oxycodone, and 69 percent of the oxymorphone quota granted by DEA. These bulk manufacturers have maintained an average inventory of 39 percent and have continually met the legitimate medical need before and during the opioid crisis. DEA has noted that dosage-form manufacturers are now validating a second API supplier as a precautionary measure. As dosage-form manufacturers continue to seek FDA approval for new drug products containing controlled substances, DEA continues to grant product development quotas to allow for qualification of two suppliers and grants quota to bulk

manufacturers to support this qualification effort.

DEA notes that the proposed regulations for procurement quota were added to the only regulation in the CFR for inventory allowance, which is located under the subheading of ''Individual Manufacturing Quotas.'' To lessen the chance of causing confusion to registrants, DEA has chosen to move the procurement quota inventory allowance regulations. As such, DEA will create new regulations to address the inventory allowance amounts for procurement quotas.

Reduction of Amount at Which Quota Would Be Suspended to 45 Percent

Issue: Many commenters explained that the reduction of the level at which quota will be suspended would require manufacturers to run smaller campaigns. They argue that this will increase the number of campaigns required to produce the same amount of product in a given year. Commenters also noted that the proposed reduced suspension amount would interfere with product supply. Commenters stated that the reduction in the suspension threshold would increase substantially the cost of bulk manufacturing and would increase the risk of shortages of API supplies and may increase the risk of diversion. They also conveyed that reducing the trigger for suspending bulk API manufacturing quota would decrease significantly the efficiency and increase the costs of bulk API manufacturers.

Commenters asked for clarification on whether the quota suspension will apply to dosage-form manufacturers and suggested that DEA clarify that it is not applicable to bulk manufacturers. They suggested that DEA apply the suspension threshold at year-end so that the inventory level is only above the trigger level briefly. Commenters conveyed that this would ensure that the suspension does not interrupt timely and efficient processing of bulk API. As an alternative option, commenters suggested that DEA clarify the definition of inventory so that it does not include material of a basic class that is not yet in finished form suitable or intended for sale or provide a more effective procedure for issuing exceptions to the quota suspension threshold.

Commenters explained that lowering the inventory ceiling to 45 percent would disrupt manufacturing operations and cause significant cost increases because this will require smaller, more frequent campaigns. They argue that these would generally decrease efficiency and potentially increase the amount of product wasted during the required cleaning of equipment between each additional campaign. Additionally, there may also be an increase in the generation of hazardous waste because of these additional campaigns. One commenter specifically stated that the reduction is too restrictive for lower volume APIs. Also, the reduction may potentially short the finished dosage-form markets by greatly impacting lead-times to get the material to customers, and it would force customers to wait an extra four to five months.

It was suggested that DEA evaluate the data throughout the year and not just the year-end data. Furthermore, DEA received suggestions that the ceiling should be set at 55 percent instead, so that drug shortages do not occur. Some commenters suggested the reduction in allowances should only apply to dosage-form manufacturers by lowering the inventory allowance for those manufacturers to 40 percent and that DEA specify that this does not apply to bulk API manufacturers.

DEA Response: DEA has been working to prevent and detect diversion for years. DEA grants the quota to companies, and they can use the quota for various purposes within the scope of their requested business activity. The companies and DEA calculate inventory allowance suspension is calculated based on the companies' estimated net-disposal for the calendar year. If the companies' dispositions are robust as estimated, the company will likely not meet the suspension percentage. If the companies' dispositions are not meeting the company's estimations as the calendar year progresses, the company will likely meet the suspension percentage and need to discontinue manufacturing until net disposition volume increases to the extent that the estimated inventory is below the inventory allowance suspension percentage. Companies can and do apply for quota revisions at any time during the calendar year. DEA grants quota to meet estimated legitimate patient need and provide an inventory allowance based for the next calendar year based on net dispositions. A company requesting quota in excess of their estimated market portion necessary to meet legitimate medical need and relevant inventory allowance, as determined by the company's supporting documentation, IQVIA data and FDA guidance, which are among the list of factors [8] DEA considers, will not receive the requested quota; however, the quota granted will be sufficient to meet legitimate need and inventory allowance. DEA has noted instances where (1) bulk manufacturers have not utilized all of their granted quota to manufacture API and have consistently held less than 50 percent in inventory; and (2) dosage-form manufacturers have requested additional quota while not distributing finished dosage-forms from their inventory to the market to cause an artificial drug shortage.

DEA wants to clarify that this final rule will be applicable to both bulk manufacturers and dosage-form manufacturers. The amount at which quota will be suspended will differ for individual manufacturing quota and procurement quota. In reviewing FDA's Orange Book by controlled substance, it is apparent the ratio of dosage-form manufacturers to bulk manufacturers is heavily weighted on dosage-form manufacturers many of whom make generic drug products that are therapeutically equivalent to other drug products for treating patients. Therefore, the dosage-form manufacturers' quota suspension level will be lower.

While DEA understands the concerns brought forth by the registrants, DEA will continue to grant quota based on legitimate need. The reduction of the suspension of quota remains based on estimated dispositions for the calendar year. This suspension does not interfere in normal campaign batches unless a company's net dispositions decrease markedly from the company's own estimated dispositions provided to DEA at the time of their quota application. A manufacturer may complete their campaigns for the calendar year based on estimated net dispositions. If dispositions are not as robust as the company predicted, then any unused quota will be suspended until dispositions are estimated to leave the company with the appropriate inventory levels at the end of the year. If the company is in the middle of a campaign batch when they realize they will exceed their estimated inventory allowance, the company can apply and request with good cause to complete the batch before suspending manufacturing activities until sales/dispositions bring the estimated inventory level to the correct percentage. *See* 1303.24(b). DEA does not control the way a company conducts business, as business decisions on production and supply chain management are done on the company level.

However, as this relates to finished dosage form manufacturers, a company who requests quota revisions because of poor business decisions, such as manufacturing unnecessary dosage-forms or strength based on estimated legitimate need for the substance,

[8] 21 CFR 1303.23 and 1315.23.

provides DEA an opportunity to grant quota based on specific FDA approved dosage-forms as authorized by the SUPPORT Act. For example, at the beginning of the COVID–19 pandemic, hospitals declared drug shortages of specific treatment drugs. DEA estimated that it granted sufficient quota to manufacturers for COVID–19 treatment drugs. DEA received additional detailed inventory information from the dosage-form manufacturers and determined that the manufacturers did not have the correct dosage forms and strengths available for hospitals to utilize immediately. Therefore, DEA granted additional quota specifically to meet the dosage forms and strengths hospitals required to treat COVID–19 patients.

Reduction of Amount at Which Requests of Additional Quota Would Be Granted to 20 Percent

Issue: Commenters requested clarification as to whether the 20 percent rule will apply to dosage-form manufacturers who use procurement quota due to its proposed placement within the CFR and because historically, DEA has said it does not apply. Many commenters opined that waiting until 20 percent to grant additional quota is too low of a threshold and would lead to supply disruption if applied to dosage-form manufacturers. The lower amount also would not allow manufacturers to be ''flexible to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that would require an increase in production of critical medications.'' Commenters went on to explain that 20 percent equals 10 weeks of inventory but production lead times are typically greater than 10 weeks. According to these commenters, waiting until there is less than 10 weeks of inventory will lead to market shortages and disrupt patient care.

The commenters went on to state that the time that it takes DEA to review quota applications is longer than six to eight weeks and granting more quota at the 20 percent mark would possibly mean depleting stock before DEA finishes reviewing. In particular, Teva stated that 15 of 36 (42 percent) of Teva's 2019 quota adjustment applications took nine weeks or longer for DEA to respond, and seven of 36 applications (19 percent) took 13–15 weeks for response. Response times of 10 or more weeks are unacceptable under normal circumstances and will exacerbate out of stock issues with reduced inventory allowances. All of this attributes to the increased potential for shortages and delays of medicine.

DEA Response: When establishing quota, DEA takes into account the current and previous year's sales and uses historical data to justify the need. DEA is not mandating that manufacturers need to have an inventory of less than 30 percent (for individual manufacturing quota) or 25 percent (for procurement quota) before applying for additional quota. A registrant may file for additional quota at any time during the calendar year. During that time, DEA will review the application and, if needed, will grant an adjustment to the quota. Registrants already apply for quota adjustments per their needs, and this will not change the current application process.

DEA acknowledges that quota processing times can vary throughout the year with some outliers. A quota processing time analysis was conducted for quota requests processed in 2019. The analysis showed a quota processing time range of four to eight weeks. When initial quotas were not factored into the calculation, the average time to process quotas was approximately 37 calendar days (estimate typical provided to registrants is four to six weeks). However, between October and December, when concomitant processing of initial and revised quota applications occur, it took an average of 57 calendar days (estimate provided to registrants is six to eight weeks). Quota processing delays can be caused by various circumstances such as, but not limited to, incomplete, poorly written, and mislabeled applications; pages of extraneous information; and extremely busy times of the year; however, inventory has historically been adequate to cover these delays and other situations.

Additionally, as previously stated, DEA has found that a portion of the procurement quota granted for some substances has not been utilized; therefore, formally establishing an inventory allowance five percent higher than that which had already been implemented should not cause more quota applications to be submitted or subsequent delays in processing. In fact, DEA showed that manufacturers have not been selling the material they have procured against their quota and instead have been adding it to their inventory to await changes in patient need.

DEA's actions in response to COVID–19 prove that even with lower inventory levels, DEA is able to be flexible to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that would require an increase in production of critical medications, despite the concerns of commenters. During the COVID–19 pandemic, DEA, FDA, other federal agencies, private partnerships, and others in the pharmaceutical industry—specifically the injectable dosage-form manufacturers—were in continuous dialogue regarding the availability of controlled substances to be used in the treatment of ventilator patients. Despite the injectable dosage-form manufacturers having almost a full year's worth of inventory, based on previous year's sales, plus current year quota on hand, hospitals reported shortages almost immediately as soon as the treatment protocols were determined. DEA soon determined that despite the sheer quantity of available inventory at the dosage-form manufacturing level, the specific formulations hospitals required were not available. In order for DEA to respond to hospitals reporting shortages of injectable products for treatment of ventilator patients during the COVID–19 pandemic, DEA and the injectable manufacturers entered into continuous dialogue to meet hospitals' demand for injectable products. With proper supporting documentation, DEA was able to process their quota requests in less than five business days, demonstrating DEA's flexibility to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that would require an increase in production of critical medications. Also, in these dialogues, injectable manufacturers stated that the manufacturing times from acceptance of API to release of the drug product took approximately 30 to 42 days. This manufacturing time further shows that manufacturers also have the flexibility to address those situations raised by the commenters.

The COVID–19 pandemic demonstrated that the issue was not the availability of large inventories on hand, but the flexibility to grant and utilize quotas to produce the formulations and dosage strengths demanded at the time of the crisis. While the inventory allowance for injectable products was not at issue, discussions with FDA and manufacturers during COVID–19 regarding cGMP issues allowed DEA to realize the importance of maintaining a separate inventory allowance for these types of products as mentioned in comments received regarding injectables.

E. Subcategories for Quotas

Issue: DEA received seven comments concerning the formalization of the current practice of use-specific subcategories for individual manufacturing and procurement quotas. One company was concerned that the

specificity may create an administrative burden on manufacturers who may need more product for one category versus another. This commenter also suggested that DEA allow registrants to transfer product between categories based on notice to DEA rather than requiring a formal reallocation of quota. Another organization emphasized that it did not object to the proposed addition of use-specific subcategories for individual manufacturing and procurement quotas and the use of subcategories by registrants. It recommends that DEA establish a new procurement quota or subcategory for CPS and opium.

An association representing manufacturers and distributors of over-the-counter medicines, dietary supplements, and consumer medical devices in the United States noted that although the subcategories for types of quotas seem workable, it would reduce flexibility. This association stated that subcategories could create inefficiencies or shortages in the supply chain if, for instance, a manufacturing batch required rework and thus required a change in which use-specific subcategory was used. The association further noted that introduction of new line extension of a medicine with a list I chemical can result in in-year shifts in the amount of material expected with little notice as development, validation or revalidation, or scale-up occur, with different sub-category quota impacts.

One commenter was concerned with how DEA defines replacement quota and whether replacement quota will be subtracted from the APQ. This same commenter questioned whether DEA intends to exceed the APQ by the issuance of additional quota to replace quota that was previously granted within the same calendar year. Additionally, the commenter suggested that DEA explain how replacement quota is factored into the APQ. As such, this commenter believes that granting replacement quota on a case-by-case can appear to be unfair when faced with identical circumstances submitted by two different manufacturers.

Another commenter requested that DEA provide clarification on whether DEA-registered manufacturers are materially impacted by the creation of new sub-categories for suppliers that will need to register for procurement quotas and would there be any additional impact to quota management and certification procedures for repackagers.

DEA Response: DEA is committed to ensuring that quotas are set in such a way as to grant manufacturers the ability to provide controlled substances to meet the demand of the legitimate medical, scientific, industrial, and research needs of the United States. DEA is required to understand what is available for legitimate patient need versus what is available for product development to calculate properly the APQ and individual quotas. Additionally, as the number of manufacturers continues to increase and industry practices and specializations change, the ability to track methodically movements of material between registrants at all stages of manufacturing becomes more critical. The specificity of quota is important. DEA is responsible for many reports that require the denotation of quantities by quota type, and it improves the efficiency of the application and reporting process for DEA-registered manufacturers. If categories are combined, there would be no way to calculate efficiently quota that was used for commercial sales, product development, packaging, etc. This would drastically inflate the quantity of commercial sales quota, as packaging/repackaging and labeling/relabeling quota, among other categories, could not be separated from commercial sales quota.

Replacement quota is intended to replace material that does not meet good manufacturing practice standards slated to meet patient needs during the current quota year and is not a means to replace disposed samples, analytical samples, product development material, and expired inventory acquired or manufactured under previous quota years. This subcategory of individual manufacturing quota and procurement quota includes quota granted to a registrant after the registrant obtained material that was initially intended for commercial sale, but is unable to be marketed. Examples include failed batches due to a contaminant, material that is out of specification and can no longer be used, lots that reached their expiration date in the supply chain, or unusable material received from a bulk manufacturer. Replacement quota is granted on a case-by-case basis. The specifics of the registrant's justification and situation determines the merit of the request.

HHS contemplates legitimate patient needs and DEA then estimates the APQ necessary to meet that need. While DEA may have granted an initial quota, changes instituted by HHS and/or market needs may demonstrate that the original quota is now higher than necessary to meet market demand. For example in November 2010, FDA asked the manufacturers of propoxyphene drug products to voluntarily withdraw their drug products due to cardiotoxicity issues. In response, DEA denied all quotas for 2011 to dosage-form manufacturers and bulk manufacturers who supplied the domestic market, and it granted substantially reduced quotas to allow manufacturers to meet the market demand of foreign countries and reference standards only. In this example, manufacturers providing just notice could exceed both agencies' estimations for legitimate need allowing for the possibility for misuse and abuse. To obtain quota, a manufacturer must submit a request to DEA for the quantity they wish to manufacture. 21 CFR 1303.12 and 130.22. DEA in turn performs a quota analysis based on the information submitted and provides a determination based on legitimate need.

Use-specific quota subcategories reflect the manufacturing activity of the applying DEA registrant and have facilitated the issuance of manufacturing and procurement quotas and provided a more accurate calculation of the APQ for the United States by preventing double counting of quota. They have been in place informally for well over a decade with no complaints from the registrants who have found the system beneficial in separating their product development and packaging efforts from their commercial manufacturing efforts when requesting adjustments to their quotas. Furthermore, packaging and repackaging are manufacturing activities as defined in the CSA and CFR and already require quota.

F. New Deadlines for the Establishment of Quotas

Issue: DEA received eight comments from the public regarding the deadline changes. Many comments were either silent on the new deadlines or either expressly stated that they had no objection for the deadline changes, with some going as far as to say they agree and understand the need to change the dates. Some desired clarification on how DEA will reconcile new deadlines for the supply chain where inconsistences have been noted. For instance, it was stated that extending the deadlines would potentially bring about supply disruptions when there are long lead times. There is also concern that changing the deadline to issue quota adjustments would represent a significant change because DEA normally issues them any time during the year, within six to eight weeks of a request. Pushing the procurement quota date to December 1 would make the manufacturing process harder with the reductions because DEA must issue procurement quota before it approves an import permit.

Response: DEA is changing the deadline for issuing initial quotas to December 1 as required in the SUPPORT Act. This new deadline will not affect the supply chain because the quota issued cannot be utilized until January 1 of the next calendar year. Initial quota applications are due to DEA by April 1 and May 1 of the preceding year to be considered in the APQ estimates which must be published before quotas are allotted. The December 1 deadline takes into account the considerable amount of information that must be collected from various sources, analyzed, and reviewed by multiple agencies prior to establishing the quota. Under the current regulations, DEA has less than two months to accomplish this task and it has proven unattainable as the controlled substance manufacturing business has grown larger and more complex. Manufacturers will still be able to apply for quota adjustments at any time throughout the calendar year. Registrants seeking an import permit need to take into account any possible delays when applying for them.

G. Letter From the States Attorneys General

Types of Quota

Issue: DEA received a letter from the Attorneys General of the States of West Virginia, Arkansas, Florida, Kentucky, Missouri, and Nebraska (hereinafter ''letter from State Attorneys General'') concerning the process for setting annual production quotas for controlled substances.

The States applauded the significant improvements DEA has made in reducing opioid production quotas over the past several years. The States stated that DEA failed to tailor the quota-setting process to legitimate medical need, and urged DEA to consider additional sources to set quotas. They further commented that there is a lack of transparency in setting quotas. The States believe that DEA needs to explain the logic behind the different approaches to set quotas.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, scientific, and export needs of the United States. DEA sets aggregate production quotas in a manner to ensure that all prescriptions that are authorized for legitimate medical purposes can be filled. For purposes of setting quotas, it should be noted that, as a result of new laws and regulations, DEA considers a number of factors, including, but not limited to, the extent of any diversion of the controlled substance in the class; relevant information obtained from HHS including FDA, CDC, CMS; and relevant information obtained from the States.[9]

SUPPORT Act

Issue: As previously stated, DEA received a letter from six State Attorneys General. West Virginia, along with five other states, urged DEA to expand the sources of data used to determine the amount of diversion that occurs. They mentioned that the SUPPORT Act and the ''Controlled Substances Quotas'' final rule (83 FR 32784) require the determination of the extent of diversion, but stated that they believe DEA takes different approaches in fulfilling this requirement. The commenters stated that DEA should estimate the diversion of *all* controlled substances the same way that DEA estimates the diversion of *covered* controlled substances. Furthermore, they want DEA to explain the logic of taking two separate approaches, as they feel that even though the wording of the two reforms slightly varies, DEA's approach should be the same.

As for the type of data DEA uses, the States suggest that DEA use national and state databases in the analysis. Specifically, they recommended three steps that DEA should take to incorporate information that is currently available: (1) Improve ARCOS and the SORS to allow greater insight into prescribing; (2) look at other national databases that track drug abuse patterns, poisonings, emergency room visits, and treatment patients; and (3) consider state databases that track drug overdoses and hospital visits.

DEA Response: As stated above, in its efforts to estimate the amount of diversion, DEA acquires data from other Federal agencies. While DEA currently utilizes multiple internal and external data sources, DEA remains open to additional sources of reliable and relevant data. Some of the sources the States suggested that DEA use are not reliable and precise and lack the required granular specificity within the data needed to estimate diversion. The data does not examine each controlled substance individually (*i.e.,* as a basic class and the quantity ingested), but groups them together chemically, making it difficult to determine which basic class was involved and to what extent its aggregate production quotas should be lowered. For example, patients that overdose from hydrocodone, oxycodone, or hydromorphone are grouped together under opioid-related overdose. DEA is unable to determine the basic class that led to the overdose from this information. Additionally, DEA cannot determine from the data if the patient overdosed on an illicit opioid or a legally marketed opioid product. For purposes of calculating the extent of diversion for each basic class of controlled substance, DEA would benefit more from the drug overdose and mortality data if it precisely identified the controlled substance(s) believed to be the cause of overdose or death and if it included the quantity of the substance ingested.

Modifications to the SORS and ARCOS reporting requirements are beyond the scope of this document. DEA did request state specific data on overdoses, death rates, and prescription data in August 2018 for consideration in setting the 2019 APQ. Only eight states provided data, none of which are represented in the comment letter; however, the data provided was not broken down by individual controlled substances, which would allow DEA to consider in determining the extent of diversion or estimating diversion.

Over-Prescribing

Issue: As previously mentioned, DEA received a comment that was co-signed by six State Attorneys General, including West Virginia. The State Attorneys General conveyed that DEA should account for over-prescribing when analyzing diversion. The commenters contend that only relying on theft and seizure records does not give a complete view of diversion. Furthermore, they suggested using the ''best practices'' of medical professionals to help account for overprescribing at the physician level. These commenters stated that medical professionals are now crafting ''best practices'' for opioid prescribing, which the states believe can aid DEA in determining correct quantities of what is ''medically necessary'' for opioids. The letter also suggests that DEA expand the National Take Back Programs to capture more data on overprescribing rates.

DEA Response: For validly dispensed controlled substances, DEA relies on physicians to use their best judgment on how much to prescribe. DEA does not establish best practices for physicians, nor does it control how much of a prescription a patient ends up consuming. DEA has previously stated that ''studies have found, with respect to a variety of medical procedures, that physicians prescribe more controlled substances for post-operative pain than the patients utilize. However, . . . DEA has concluded that while the referenced studies are concerning, they are

[9] 21 U.S.C. 826(a); 21 CFR 1303.11.

insufficient to support a determination as to the level of overprescribing that occurs across the range of the medical procedures that are performed each year on a national basis.'' [10] More recently, DEA has found that physicians are already prescribing at lower rates because of healthcare guidance.

As previously stated, there has been a decline in schedule II opioid prescriptions since 2014. Currently, there is no reliable method for quantifying the amount of prescription medications turned in to the Take-Back program. DEA found one study from 2015 that attempted to quantify the drugs received at one Take-Back location titled, ''Analysis of Medications Returned During a Medication Take-Back Event.'' However, DEA believes that this study is not useful because the methods drastically affect/limit the quantity of each substance that could be included in the analysis. To be included in the study, the medication had to have the following identifiers: drug name, strength, amount remaining, amount prescribed, generic or brand, and source (local pharmacy, mail-order pharmacy, or sample). The study also excluded medications unavailable in the United States, pet medications, medications in containers without a legible label, containers with remaining medication amounts larger than the amount dispensed, and medications not in tablet or capsule formulations. The study authors were able to demonstrate an average overprescribing rate for all medication types of 66 percent based on the total number of pills dispensed (obtained from labels) and the total number of pills remaining in the containers; however, substance specific information is not available because the medications (controlled and non-controlled) were grouped. The study does not mention the proportion of medicine excluded from the study or an estimate of diversion of particular substances. The study assumed that over prescribing was the cause of the remaining number of tablets in the bottle based on the written prescription. It also assumed that the remainder in the bottle was legitimate; however, neither of these assumptions may be the case. The bottle may have contained the remainder of multiple prescriptions of the same drug product dispensed over time and brought to the drug Take-Back event in a single container. This single study cannot be extrapolated to the national level for use in estimating diversion or overprescribing.

H. Out of Scope

DEA received 194 comments are that are being considered out of scope in their entirety or partially. These comments were very general and mentioned personal medical issues, treatments, medication costs, and drug shortages. Included in these general out of scope comments were assertions that illicit drug use is the problem and that doctors are not treating patients due to fear of punishment from DEA.

DEA remains committed to ensuring that there is an adequate and uninterrupted supply of control substances to meet the legitimate medical, scientific, and export needs of the United States. DEA does not tell manufacturers how to manage their quota within the use-specific categories. For example, if a manufacturer holds an FDA-approved application for several different strengths of a dosage-form drug product, DEA will not dictate which strengths it should manufacture. Furthermore, as previously stated, DEA does not plan to set APQ in terms of pharmaceutical dosage-form. As such, the FDA-approved dosage-forms and strengths that a manufacturer produces are solely based on the manufacturers' decision. In the event of shortages of specific dosage-forms and/or strengths of a dosage-form, DEA has and will continue to implement actions based on quota to prevent or alleviate a drug shortage; however, DEA notes that the injectable shortage is not a quota issue, but instead due to manufacturers not complying with FDA's cGMP requirements. In fact, DEA has granted quota to manufacturers seeking to comply with FDA requirements. If DEA receives reliable information of a manufacturer refusing to manufacture a dosage-form or strength to alleviate a drug product shortage, DEA will implement its authority under the SUPPORT Act to issue the manufacturer's quota in terms of dosage-form and/or strength to ensure that manufacturers produce certain dosage-forms to assist in alleviating the drug shortage.

III. Provisions Implemented in the Final Rule

A. Types of Quota

DEA is adding sections 21 CFR 1303.03, 1303.17, 1315.06, and 1315.37, and revising 1303.27 and 1315.27 to introduce and define the types of quotas in the current quota system and to clarify and update the method to abandon both individual manufacturing and procurement quotas. Section 21 CFR 1303.03 will define the three types of quota for schedule I and II controlled substances: APQ, individual manufacturing quotas, and procurement quotas. Section 21 CFR 1315.06 will define the four types of quotas available for list I chemicals: AAN, individual manufacturing quotas, procurement quotas, and import quotas.

To strengthen the quota management process, DEA has turned to managing many aspects of the quota system online. With this final rule, DEA will update 21 CFR 1303.27 and 1315.27 to require manufacturers submit a quota application to the UN Reporting and Quota Section in the online Quota Management System instead of submitting to the Drug and Chemical Evaluation Section a written notice to abandon any or all parts of the individual manufacturing quotas for schedule I and II controlled substances and list I chemicals.

Sections 1303.17 and 1315.37 will clarify that a manufacturer must also abandon procurement quota for schedule I and II controlled substances and list I chemicals using the online Quota Management System. Current regulations only refer to the abandonment of individual manufacturing quota. To further clarify the CFR, DEA will separate the current subsection within the controlled substance quota regulations entitled ''Aggregate Production and Procurement Quotas'' and will make a separate subsection for ''Procurement Quotas.'' In accordance with the creation of this new subsection, DEA will move 21 CFR 1303.12 to 1303.15 and reserve 1303.12 for future use. These additions and changes are also required due to the procurement quota inventory allowances that are being finalized with this rule.

B. SUPPORT Act

As previously discussed in the NPRM, as well as above in Section II, DEA will be implementing in its regulations the amendments to the CSA made by the SUPPORT Act. These amendments include the authority to establish APQ, individual manufacturing quotas, and procurement quotas in terms of pharmaceutical dosage-forms, if it is determined that it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance, which will be added to DEA's regulations at 21 CFR 1303.11(a), 1303.12(a) and 1303.21(a). DEA will also be revising 21 CFR 1303.21(a) and 1315.21 to change the date to on or before December 1 by which individual manufacturing quotas must be fixed.

[10] *Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2019.* 85 FR 67348 at 67350. December 28, 2018.

DEA will be adding a new regulation regarding the requirement to estimate the amount of diversion of the five covered controlled substances in the United States when establishing quotas for these controlled substances and make appropriate reductions will be added to 21 CFR 1303.05. Furthermore, this regulation will codify the requirements of the SUPPORT Act regarding information to be considered when estimating diversion. The SUPPORT Act requires consultation with the Secretary of HHS in any year that the approved APQ for a covered controlled substance is higher than that of the previous year and an explanation from DEA in the APQ final order of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States 21 U.S.C. 826(i)(2)(A). These requirements will also be included in 1303.05, along with the definition of a covered controlled substance.

C. Procurement Quota

Sections 1303.12(f) and 1315.32(h) currently require certificates of quota only when purchasing from a manufacturer. Currently, DEA manages the quota process by providing each manufacturer a letter stating the quantity of controlled substance(s) and/or list I chemical(s) the manufacturer may obtain during a calendar year. This letter provides legal documentation that the manufacturer is authorized to obtain a specified quantity of the controlled substance(s) and/or list I chemical(s). When the CSA and DEA's regulations were first promulgated, neither contemplated that distributors would be used to move controlled substances and list I chemicals between manufacturers.

When distributors provided schedule II controlled substances to this subset of manufacturers without verification of the manufacturers' quota authorization, it circumvented the quota process of verifying quota to the supplier. This prevents DEA from performing its oversight responsibilities and leads to unauthorized distribution of drug products. These unauthorized distributions are only noted as sales, which artificially inflates the estimation of legitimate medical need, a heavily weighted factor in the setting and revising of the APQ.

This final rule revises 21 CFR 1303.12(f) and 1315.32(h) by ensuring that both manufacturers and distributors are required to obtain certification of a buyer's quota for the requested schedule I and II controlled substances, as well as list I chemicals when the buyer is a manufacturer. By requiring that all manufacturers and distributors receive a certification of quota before providing any quantity of controlled substance or list I chemical to a DEA registered manufacturer, DEA is better able to maintain the closed distribution system.

D. Inventory Allowance

DEA is revising 21 CFR 1303.24 and 1315.24 to reduce the overall inventory held by DEA-registered bulk and dosage-form manufacturers. In response to the comments received, DEA will create a new regulation to address the procurement quota changes. DEA had proposed to place the changes for procurement quotas in 21 CFR 1303.24 and 1315.24; however, it was pointed out that the proposed placements fall under the ''Individual Manufacturing Quota'' subsections. As such, DEA will create two new regulations, 21 CFR 1303.16 and 1315.31 and will place them within the appropriate procurement quota subsections.

DEA also acknowledges the concerns conveyed in the comments regarding the proposed percentages being too restrictive. In response to these concerns, DEA conducted further analyses on dosage-form manufacturer inventory data. As previously stated, the data showed that manufacturers only acquired 72.7 percent of fentanyl, 73.9 percent of hydrocodone, 56.7 percent of hydromorphone, 79.3 percent of oxycodone, and 73 percent of oxymorphone from the quotas granted to them by DEA. As prescription rates have fallen, DEA has issued lower quotas to match the estimated fallen rates. The data show that even with the reduced quotas, the material has not sold, but has been placed into inventory, thereby significantly increasing inventory levels above that which is medically necessary on an annual basis. DEA has found that over the past years, inventory levels have averaged 72 percent for fentanyl, 36.9 percent for hydrocodone, 57 percent for hydromorphone, 36.3 percent for oxycodone, and 61 percent for oxymorphone, while still meeting legitimate medical needs. The inventory levels for fentanyl, hydromorphone, and oxymorphone include product development efforts as manufacturers seek FDA approval of abuse-deterrent formulations. This data suggests that the current allowance of 30 percent was not too restrictive and has allowed manufacturers to acquire the quota they need for commercial sales. However, in light of the need for preparedness for any contingencies, DEA will establish the procurement quota inventory allowance at 35 percent.

DEA is also taking the time to clarify what changes will apply to bulk form manufacturers and dosage-form manufacturers. Bulk manufacturers receive individual manufacturing quotas and dosage-form manufacturers receive procurement quota. DEA acknowledges the concerns of manufacturers, but for reasons stated above, a lower inventory allowance for individual manufacturing quota needs to be implemented. As such, DEA has reviewed historical data from the companies and determined that 50 percent (six months) of inventory allowance is no longer necessary given the changes in prescribing guidelines to meet legitimate medical need and will be reducing individual manufacturing quota inventory allowances to 40 percent instead. The reduction to 40 percent allows for just under five months of inventory and takes into account the latest prescribing practices of the most prescribed substances as well as decreasing the likelihood of diversion of stocks. It still allows manufacturers the flexibility to accommodate market changes, FDA regulations, and unforeseen circumstances. As previously discussed for procurement quotas, there are more dosage-form manufacturers than bulk manufacturers; therefore, a lower inventory allowance for procurement quota is warranted. For procurement quotas, DEA will establish (for controlled substances) and will reduce (for list I chemicals) inventory allowances to 35 percent (instead of 30 percent), except in the circumstances of liquid injectable dosage-forms. Liquid injectable dosage-forms (injectable products, vials, solution bags, but not tablets, capsules, suppositories, patches, films, and oral solutions) will continue to receive a 50 percent inventory allowance due to DEA's acknowledgement that there are less dosage-form manufacturers for these liquids, as addressed above. Instead of suspending all quota when a registrant's inventory exceeds the proposed amount of 45 percent, DEA will be finalizing three different suspension amounts. The amount at which quota will be suspended for manufacturing quota is when the inventory reaches 55 percent and will remain suspended until the amount is lower than 50 percent. For all dosage-forms, except liquid injectable dosage-forms, individual procurement quota will be suspended at 50 percent and will be reinstated when the amount is less than 45 percent. As applied to liquid injectable dosage-forms,

individual procurement quota will be suspended at 65 percent and will remain in suspension until the inventory amount is lower than 60 percent. Last, instead of DEA granting requests of additional quota if inventory is less than the proposed 20 percent, DEA again will be finalizing three different amounts based on type of quota. DEA may increase the amount of individual manufacturing quota once the inventory is less than 30 percent. For individual procurement quota, the amount of quota may be increased when the inventory is less than 25 percent; however, individual procurement quota for liquid injectable dosage-forms may be increased when the inventory is less than 40 percent.

The final changes are as follows:

- 21 CFR 1303.16(a)—establishes an inventory allowance issued by DEA for procurement quotas of 35 percent for all dosage-forms of schedules I and II controlled substances, except liquid injectable dosage-forms, which will receive an inventory allowance of 50 percent;
- 21 CFR 1303.16(b) and (c)—suspends procurement quota issued by DEA if inventory exceeds 50 percent for all dosage-forms of schedules I and II controlled substances, except liquid injectable dosage-forms, which will be suspended if inventory exceeds 65 percent;
- 21 CFR 1303.16(d) and (e)—may grant request for additional procurement quota by registrant if inventory is less than 25 percent for all dosage-forms of the registrant's estimated net disposal for schedules I and II controlled substances, except liquid injectable dosage-forms, which may be granted if inventory is less than 40 percent;
- 21 CFR 1303.24(a)—decreases the inventory allowance issued by DEA for individual manufacturing quotas from 50 to 40 percent for schedules I and II controlled substances;
- 21 CFR 1303.24(b)—suspends individual manufacturing quota issued by DEA if inventory exceeds 55 percent of the registrant's estimated net disposal for schedules I and II controlled substances;
- 21 CFR 1303.24(c)—may grant request for additional individual manufacturing quota by registrant if inventory is less than 30 percent of the registrant's estimated net disposal for schedules I and II controlled substances;
- 21 CFR 1315.24(a)—decreases the inventory allowance issued by DEA for individual manufacturing quotas from 50 to 40 percent for the list I chemicals;
- 21 CFR 1315.24(b)—suspends individual manufacturing quotas issued by DEA if inventory exceeds 55 percent of the registrant's estimated net disposal for the list I chemicals;
- 21 CFR 1315.24(c)—may grant request for additional individual manufacturing quotas by registrant if inventory is less than 30 percent of the registrant's estimated net disposal for the list I chemicals;
- 21 CFR 1315.31(a)—decreases the inventory allowance issued by DEA for procurement quotas from 50 to 35 percent for all dosage-forms of the list I chemicals, except liquid injectable dosage-forms, where an inventory allowance of 50 percent will be created;
- 21 CFR 1315.31(b) and (c)—suspends procurement quotas issued by DEA if inventory exceeds 50 percent for all dosage-forms of the registrant's estimated net disposal for the list I chemicals except liquid injectable dosage-forms, which will be suspended if inventory exceeds 65 percent; and
- 21 CFR 1315.31(d) and (e)—may grant request for additional procurement quotas by registrant if inventory is less than 25 percent for all dosage-forms of the registrant's estimated net disposal for the list I chemicals, except liquid injectable dosage-forms, which may be granted if inventory is less than 40 percent.

E. Subcategories

DEA is formalizing the addition of use-specific subcategories by adding 21 CFR 1303.04 and 1315.07. As a practical matter, DEA acknowledges that these subcategories are already in use through voluntary and cooperative efforts of DEA registrants. This final rule will codify DEA's current utilization of subcategories while facilitating the issuance of individual manufacturing and procurement quotas.

Additionally, the specification of subcategories for manufacturing and procurement quotas provides benefits to the registrant by allowing for a more detailed level of communication with DEA as to why a registrant requires specific controlled substances and list I chemicals and how the registrant will utilize those substances.

As the number of manufacturers continues to increase and industry practices and specializations continue to evolve, DEA's ability to track movement of material between registrants at all stages of manufacturing is critical.

F. Deadlines

DEA collects various data to administer the quota system and moving the deadlines will allow more time for processing the numerous applications that DEA receives and for responding to applications for quota, as there are more registrants now than there were when the regulations were first promulgated. The new deadlines will also allow DEA more time to obtain additional relevant data from multiple agencies. The changes are as follows:

- Establishment of the APQ and the AAN (21 CFR 1303.11(c) and 1315.11(c)): change from May 1 to September 1;
- Deadline to issue procurement quota (21 CFR 1303.12(c) and 1315.32(f)): change from July 1 to December 1;
- Deadline to issue import quota for list I chemicals (21 CFR 1315.34(f)): change from July 1 to December 1; and
- Deadline to adjust individual manufacturing quota (21 CFR 1303.23(c) and 1315.23(c)): change from March 1 to July 1.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This final rule has been developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, public health and safety, and environmental advantages, distributive impacts, and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action'' requiring review by the Office of Management and Budget (OMB) as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

While this final rule is not economically significant, it is a significant regulatory action under E.O.

12866, section 3(f) subjecting it to review by OMB. DEA analyzed the economic impact of each provision of this final rule, including any changes made from the proposed rule, and estimated the annual cost to be $26.4 million. Certain provisions are estimated to have benefits; however, DEA does not have a basis to estimate those benefits due to many unknowns. Because of this, the benefits of this rule are discussed qualitatively. The rule contains clarification of regulatory language and the codification of existing DEA and registrant practices regarding subcategories for quotas, certification of procurement quota, reductions to inventory allowances, and additional considerations for revisions to the APQ. The results of the analysis of each provision are as follows:

Defining Types of Quota and Filing To Abandon Quota

These provisions simply codify existing DEA practices, and will result in no economic impact on registrants or DEA. The formal definition of quota types will have no economic impact on registrants or DEA, and formalizing the procedure to abandon quota is simply a codification of DEA's current procedure. While these provisions will have no quantifiable impact, DEA believes there is at least a minimal benefit to codifying existing practices accurately. Because these provisions codify existing practice, current registrants are, in most cases, already complying and will not change their behavior. Errors and misunderstandings on the part of registrants do happen, but are uncommon. Nevertheless, these provisions of the final rule are expected to enhance clarity, certainty, and efficiency.

Conforming Revisions Related to the SUPPORT Act

As indicated above, the SUPPORT Act gives DEA discretionary authority to establish quotas in terms of pharmaceutical dosage-form. At the present time, DEA is not deviating from its current practice of establishing quotas necessary for the manufacture of finished dosage-forms in terms of kilograms and allowing manufacturers to determine how best to allocate those kilograms to different FDA-approved dosage-forms. While it is impossible to know all the circumstances in which this authority might be utilized in the future, it is DEA's current intention that any implementation of dosage-form quotas will be the exception rather than the rule and will coexist alongside kilogram quotas. DEA recognizes that dosage-form manufacturers are in the best position to understand the demand for their products, in dosage-form. Because, at the present time, DEA is likely to use this authority sparingly, and only adjust quotas for manufacturers producing the dosage-form, DEA anticipates that this provision of the proposed rule will have minimal impact.

The SUPPORT Act also requires DEA to estimate the amount of diversion when establishing quota for a covered controlled substance using all reliable information, including information from HHS and other agencies. DEA has considered information and data regarding the amount of diversion for covered controlled substances when applicable during the process of determining the APQ. This function is a regular part of DEA's operations, although in the past DEA has relied on its own internal data in the process of determining the APQ. DEA's view is that considering additional reliable information gathered from outside the agency to estimate the amount of diversion will result in minimal additional time or cost.

The SUPPORT Act updates also extend DEA's deadline to fix individual manufacturing quotas for schedules I and II controlled substances from October to December, and they formally define the phrase ''covered controlled substance'' to include fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone. The deadline extension will have minimal impact on registrants, as DEA currently does not meet the October deadline and has not met that deadline since before 1996. This extension will align the regulations with reality for registrants and DEA. Defining ''covered controlled substance'' will not change how those substances or the registrants that are authorized to handle those substances are regulated. Therefore, these provisions will have minimal impact on registrants or DEA.

While the benefits of the SUPPORT Act updates were not quantified due to many unknowns, it is possible to discuss some of these benefits in qualitative terms. With these conforming revisions related to the SUPPORT Act, DEA has the ability to respond to adverse market conditions with increased speed and flexibility to minimize public harm. DEA would use dosage-form quotas to alleviate the rare occurrence of a drug shortage in the market by targeting the specific dosage-forms that are in short supply instead of simply increasing the total amount of kilograms of a drug to be produced, resulting in a benefit to the public. Another benefit is that updating the deadlines for setting individual manufacturing quotas so they reflect DEA's current practice eliminates regulatory uncertainty for manufacturers. Regulations that realistically reflect current DEA and industry practice will benefit the planning processes of current and future market participants.

Procurement Quota Certification

The final rule will require that all DEA registrants supplying schedules I and II controlled substances and list I chemicals to DEA manufacturers obtain certification of the manufacturer's quota before completing the transaction. In practice, this certification may be any written declaration issued by manufacturers to distributors. This provision prevents manufacturers from purchasing their API or finished dosage-forms from distributors without quota verification as currently required when manufacturers request API or finished dosage-forms from other manufacturers. Current regulations stipulate that only entities registered as ''importer,'' ''manufacturer,'' or ''bulk manufacturer'' must certify quota before a sale.[11]

To estimate the cost of this provision, DEA utilized internal data tracking the sale of schedules I and II controlled substances and list I chemicals from distributors to manufacturers during the three year period of January 1, 2015 to December 31, 2017. DEA's analysis revealed that over this three year period, distributors filled an average of 3,000 orders to manufacturers per year. Using Bureau of Labor Statistics (BLS) wage data for Compliance Officers,[12] the type of registrant employee that would be tasked with certifying quota, DEA estimated the labor cost of quota certification to distributors and manufacturers. Based on its knowledge of registrant business operations, DEA estimates a manufacturer compliance officer requires 10 minutes to draft a quota certification letter after placing a purchase request to a distributor, while the distributor compliance officer requires five minutes to review and verify the manufacturer's certification letter. This results in a combined labor burden of 15 minutes (0.25 hours). Multiplying the loaded median hourly wage rate for compliance officers [13] by

[11] 21 CFR 1303.12(f) and 1315.32(h).

[12] For the purposes of this analysis, DEA used the median hourly wage rate of $32.63 for 13–1041 Compliance Officers. Bureau of Labor Statistics, Occupational Employment and Wages, May 2017, *https://www.bls.gov/oes/2017/may/oes131041.htm.*

[13] The loaded hourly rate for 13–1041 Compliance Officers is $46.99 ($32.63 × 1.44). Bureau of Labor Statistics, Employer Costs for

Continued

0.25 and applying that to the estimated 3,000 certification letters per year yields a combined annual labor cost of $35,241 ($23,494 of which is incurred by manufacturers while the remaining $11,747 is incurred by distributors).

Reduction of Inventory Allowances

In response to public comments regarding the proposed inventory allowance reductions put forth in the NPRM, DEA is modifying the reductions that will become effective upon publication of this final rule, while also establishing new procurement quota inventory allowances for dosage forms. Comments received from manufacturers stressed that the proposed changes to the inventory allowance would increase production costs, product waste, and inefficiencies. Specifically, manufacturers stated that the proposed reductions would require smaller, more frequent manufacturing campaigns in order to produce the same amount of finished product in a given year, and that DEA's ability to respond to requests for quota adjustments throughout the year is not sufficient if market demand fluctuates. Additionally, commenters expressed concern that reducing inventory allowances for certain liquid injectable dosage-forms may cause a significant disruption in the supply of these life-saving drugs given the relatively limited number of manufacturers. As a result, DEA is adjusting the inventory allowance reductions in this final rule to minimize, to the extent possible, any supply disruptions or increases in manufacturing production costs. DEA is also clarifying which inventory allowances apply to individual manufacturing quota and which apply to procurement quota by establishing a procurement quota inventory allowance in 21 CFR 1303.16(a). While there may not be published studies showing that smaller inventories reduce diversion, DEA must provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks, while also preventing an oversupply which increases the risk of diversion. DEA believes that these final inventory allowance reductions will help achieve its goal of reducing the risk of diversion at the manufacturer level.

Many of the comments received from manufacturers stated generally that the proposed inventory allowance reductions would increase the cost of API production, but only one commenter provided a detailed estimate for how much their costs are likely to increase in a given year. This commenter estimates that their incremental production costs would rise by approximately $600,000 per year, primarily due to the reduced inventory allowance necessitating an additional manufacturing campaign for their largest volume API products, decreasing efficiency and potentially increasing the amount of product wasted during the required cleaning of equipment between each additional campaign. While DEA recognizes this single cost estimate as legitimate, it is unlikely that production costs are uniform across manufacturers and depend largely on variables unique to each firm. However, given the absence of detailed monetary cost estimates from other commenters, and the fact that the required inputs to calculating an individual firm's manufacturing costs are proprietary and unknown to DEA, using this commenter's estimate as the basis for estimating the impact of this provision of the final rule is the most reasonable option available to DEA.

With this final rule, DEA will be reducing individual manufacturing quota inventory allowances to 40 percent (instead of the proposed 30 percent) and will be establishing (for controlled substances) and reducing (for list I chemicals) procurement quota inventory allowances for all dosage-forms (except liquid injectable dosage-forms) to 35 percent. Procurement quota inventory allowances for liquid injectable dosage-forms are being formally established at 50 percent, resulting in no change from the pre-rule baseline. The threshold at which individual manufacturing quota will be suspended is reached when inventories exceed 55 percent of estimated net disposal (instead of the proposed 45 percent) and will remain suspended until inventory falls below 50 percent. However, DEA will suspend individual procurement quota at 50 percent, and will reinstate it when inventories fall below 45 percent. DEA will suspend procurement quota for liquid injectable dosage-forms when inventories rise above 65 percent, and will reinstate it when inventories fall below 60 percent. Finally, DEA may increase the amount of individual manufacturing quota once the inventory is less than 30 percent (instead of the proposed 20 percent). For individual procurement quota, the amount of quota may be increased when the inventory is less than 25 percent or when inventories are less than 40 percent for liquid injectable dosage-forms.

Because the comments received from manufacturers focused primarily on their estimation of the increase in time and cost of manufacturing API products, DEA believes it is reasonable to assume that the costs imposed by this provision stem primarily from the inventory allowance reduction for individual manufacturing quotas, and this cost is borne by bulk manufacturers. There are currently 44 bulk manufacturers registered with DEA. Based on the only detailed monetary cost estimate received, DEA assumes that each of these registrants will incur an average annual cost of $600,000, equating to $26.4 million in total annual costs as a result of this provision of the final rule.

It is important to note that the estimated total annual costs from reducing inventory allowances could be higher than actual costs. The incremental cost increase of $600,000 presented by the commenter and being used in this analysis as representative of the average annual costs for each bulk manufacturer was based on the proposed individual manufacturing quota inventory allowance reduction from 50 percent to 30 percent, with suspension of quota at 45 percent. As stated above, based on public comments, DEA is choosing to implement a smaller reduction to inventory allowances with this final rule, settling on an individual manufacturing quota inventory allowance of 40 percent, with suspension of quota occurring if inventories rise above 55 percent. Additionally, the commenter that provided the monetary cost estimate is a large manufacturer; therefore, applying their estimated costs across all 44 bulk manufacturers, which includes many small manufacturers, likely overstates the total annual cost. Because of this, it may be the case that the average incremental costs incurred by bulk manufacturers are less than $600,000, especially if the revised inventory allowances prevent the need for some manufacturers to add production campaigns for certain products. However, DEA has no way of knowing if this is indeed the case; therefore, DEA assumes that an average annual cost estimate of $600,000 incurred by bulk manufacturers as a result of this provision is reasonably accurate.

Inventory allowances are a factor in DEA's determination of a registrant's quota for the coming year and provides inventory for sales at the beginning of a new quota year before quota is received. Registrants may also exceed their

Employee Compensation—December 2018, *https://www.bls.gov/news.release/archives/ecec_12142018.pdf.*

inventory allowance during the year. If at any time during the year, the inventory of a basic class held by a manufacturer exceeds 55 percent (or 50 percent for procurement quota of dosage-forms) of estimated net disposal, the quota for that class is automatically suspended and would remain suspended until inventory is less than 50 percent (or 45 percent for procurement quota of dosage-forms) of the estimated net disposal. Practically speaking, the changes to inventory allowances equate to a reduction from the current half of a year's sales supply (50 percent) allowed to be held as inventory to nearly five months (40 percent) for individual manufacturing and over four months (35 percent) for dosage-form manufacturing. Additionally, the 55 percent maximum inventory during the year would give manufacturers the flexibility to have over six months of sales supply inventoried to account for any unplanned fluctuations in demand or timing in orders for their product throughout the year. For dosage-form manufacturers, the maximum inventory of 50 percent provides exactly six months of sales supply. The inventory allowance for liquid injectable dosage-forms remains unchanged; thus, there is no impact on these products.

While DEA acknowledges that reducing inventory allowances will increase costs for bulk manufacturers, DEA concludes that these reductions are not likely to result in supply disruptions. Registrants routinely request adjustments to their quota throughout the year due to fluctuations in market conditions, and this is a normal part of a manufacturer's business operations. DEA quickly responds to these requests within six to eight weeks, ensuring legitimate business is not disrupted, and will continue to do so once this rule is promulgated. For example, in 2017 (the last year in which data are available), DEA processed 1,752 initial quota applications and 2,299 requests for adjustment to quota. Additionally, in response to the ongoing COVID–19 pandemic, DEA and manufacturers of injectable products for treatment of ventilator patients have entered into continuous dialogue to meet surging hospital demand. During this time, DEA was able to process manufacturer quota requests in less than five business days, demonstrating DEA's flexibility to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that would require an increase in production of critical medications. Also, in these dialogues, injectable manufacturers stated that the manufacturing times from acceptance of API to release of the drug product took approximately 30 to 42 days. The COVID–19 pandemic has demonstrated that the flexibility to grant and utilize quotas to produce the formulations and dosage strengths demanded in times of crisis is more important than the availability of large inventories on hand.

Formalization of Subcategories for Manufacturing Quotas and Procurement Quotas

This provision of the final rule is a codification of existing voluntary and cooperative efforts between registrants and DEA that have been in place since 2001 and facilitates a more accurate calculation of APQ for the United States. The establishment of subcategories of: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling are already being utilized by DEA with full cooperation from all registrants. Therefore, this provision simply updates 21 CFR 1303.03, 1303.04, 1315.06, and 1315.07 to reflect current DEA procedure for the management of quota, and it will have no economic impact on registrants or DEA.

New Deadlines for Establishing Quotas

The final rule will modify the deadlines for establishing and publishing the APQ, AAN, import quotas, procurement quotas, manufacturing quotas, and any adjustments to manufacturing quotas. Due to the expansion of the market and the increase in the number of bulk and dosage-form manufacturers since that deadline was implemented almost 50 years ago, DEA frequently misses the current deadlines for the establishment of the APQ and the AAN of May 1 and the issuing of individual procurement, manufacturing and import quotas of July 1. Congress mandated quotas for importers of list I chemicals in 2007.[14] Applications for import and procurement quota are due April 1, giving DEA only 30 days before the May 1 deadline for publication of the APQ and AAN. Given that DEA has historically missed these deadlines since it must take adequate time to provide a thorough and careful assessment of each application, both DEA and industry have already become accustomed to a delayed publishing schedule. Therefore, this provision is expected to have minimal economic impact as it simply aligns the regulatory deadlines with the current practices of DEA and industry.

Executive Order 12988, Civil Justice Reform

This rulemaking meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State, or diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. DEA's evaluation of economic impact by size category indicates that this final rule will not have a significant economic impact on a substantial number of these small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities and discussions of its findings are below.

As discussed in the ''Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)'' section above, this rule has six key components as described below.

Defining Types of Quota and Filing To Abandon Quota

This provision codifies existing DEA practices and will result in no economic

[14] Combat Methamphetamine Epidemic Act of 2005, Public Law 109–177.

impact on registrants or DEA. The formal definition of quota types will have no practical impact on registrants, and formalizing the procedure to abandon quota is simply a codification of DEA's current procedure. Therefore, this provision will have no costs.

Conforming Revisions Related to the SUPPORT Act

While the SUPPORT Act gives DEA the authority to establish quotas in terms of pharmaceutical dosage-form, DEA will continue to use its current process of establishing quota in terms of kilograms. Therefore, this provision of the rule will have no impact.

Additionally, the SUPPORT Act defines the phrase ''covered controlled substance'' to include fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone. It requires DEA to estimate the amount of diversion when establishing quota for covered controlled substances by consulting with the Secretary of HHS and considering reliable information on the rates of overdose deaths and abuse and overall public health impact in the United States that is determined to be reliable. DEA has considered the amount of diversion when establishing quotas when data has been available and is a regular part of DEA's operations. Therefore, considering additional reliable information gathered from outside the agency to estimate the amount of diversion will result in minimal additional cost.

The SUPPORT Act updates also extend DEA's deadline to fix individual manufacturing quotas for schedules I and II controlled substances from October to December. The deadline extension will have minimal impact on registrants as DEA currently does not meet the October deadline. This extension will align the regulations with reality for registrants. Therefore, these provisions will have minimal impact on registrants or DEA.

Procurement Quota Certification

The final rule will require that all DEA registrants supplying schedules I and II controlled substances and list I chemicals to DEA manufacturers to obtain certification of the manufacturer's quota before completing the transaction. In practice, this certification must be a written declaration issued by manufacturers to distributors containing the information as required in the regulations.[15] This provision prevents manufacturers from purchasing their API or finished dosage-forms from distributors without quota verification as currently required when manufacturers request API or finished dosage-forms from other manufacturers. Current regulations stipulate that only entities registered as ''importer,'' ''manufacturer,'' or ''bulk manufacturer'' must certify quota before a sale.[16]

To estimate the cost of this provision, DEA utilized internal data tracking the sale of schedules I and II controlled substances and list I chemicals from distributors to manufacturers during the three year period of January 1, 2015 to December 31, 2017. DEA's analysis revealed that over this three year period, distributors filled an average of 3,000 orders to manufacturers per year. Using BLS wage data for Compliance Officers, the type of registrant employee that would be tasked with certifying quota, DEA estimated the labor cost of quota certification to distributors to be $11,747 and $23,494 to manufacturers, resulting in a combined annual labor cost of $35,241.

Reduction of Inventory Allowances

This final rule will reduce the inventory allowance for manufacturers of controlled substances and list I chemicals from 50 percent to 40 percent of the registrant's estimated net disposal, and it will establish a procurement quota inventory allowance for dosage-forms and list I chemicals at 35 percent of the registrant's estimated net disposal. Procurement quota inventory allowances for liquid injectable dosage-forms are also being formally established at 50 percent, resulting in no change. Inventory allowances are a factor in DEA's determination of a registrant's quota for the coming year and provide inventory for sales at the beginning of a new quota year before quota is received. Registrants may exceed their inventory allowance during the year. If at any time during the year the inventory of a basic class held by a manufacturer exceeds 55 percent (or 50 percent for procurement quota for dosage-forms) of estimated net disposal, the quota for that class is automatically suspended and would remain suspended until inventory is less than 50 percent (45 percent for procurement quota dosage-forms) of the estimated net disposal. Practically speaking, the changes to inventory allowances equate to a reduction from the current half of a year's sales supply (50 percent) allowed to be held as inventory to nearly five months (40 percent) for individual manufacturing and over four months (35 percent) for dosage-form manufacturing. Additionally, the 55 percent maximum inventory during the year gives manufacturers the flexibility to have over six months of sales supply inventoried to account for any unplanned fluctuations in demand or timing in orders for their product throughout the year. For dosage-form manufacturers, the maximum inventory of 50 percent provides exactly six months of sales supply. The inventory allowance for liquid injectable dosage-forms remains unchanged at 65 percent; thus, there is no impact on these products.

Because the comments received from manufacturers on this provision of the proposed rule focused primarily on their estimation of the increase in time and cost of manufacturing API products, DEA believes it is reasonable to assume that any costs imposed by this provision stem primarily from the inventory allowance reduction for individual manufacturing quotas, and this cost is borne by bulk manufacturers. The only commenter to provide a detailed monetary cost estimate for DEA to consider stated that its incremental production costs would rise by approximately $600,000 per year primarily due to the reduced inventory allowance necessitating an additional manufacturing campaign for their largest volume API products. While DEA recognizes this single cost estimate as legitimate, it is unlikely that production costs are uniform across manufacturers and depend largely on variables unique to each firm. However, given the absence of detailed monetary cost estimates from other commenters and the fact that the required inputs to calculating an individual firm's manufacturing costs are proprietary and unknown to DEA, using this commenter's estimate as the basis for estimating the impact of this provision of the final rule is the most reasonable option available to DEA.

There are currently 44 bulk manufacturers registered with DEA. DEA assumes that each of these registrants will incur an average annual cost of $600,000, equating to $26.4 million in total annual costs because of this provision of the final rule.

While DEA acknowledges that reducing inventory allowances will increase costs for bulk manufacturers, DEA concludes that these reductions are not likely to result in supply disruptions. Registrants also routinely request adjustments to their quota throughout the year due to fluctuations in market conditions. This is a normal part of a manufacturer's business operations. DEA quickly responds to these requests within six to eight weeks, ensuring legitimate business is not

[15] 21 CFR 1303.12(f) and 1315.32(h).

[16] *Id.*

disrupted, and it will continue to do so once this rule is promulgated. For example, in 2017 (the last year in which data are available), DEA processed 1,752 initial quota applications and 2,299 requests for adjustment to quota. Additionally, in response to the ongoing COVID–19 pandemic, DEA and manufacturers of injectable products for treatment of ventilator patients entered into continuous dialogue to meet surging hospital demand. During this time, DEA was able to process manufacturer quota requests in less than five business days, demonstrating DEA's flexibility to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that could require an increase in production of critical medications. Also, in these dialogues, injectable manufacturers stated that the manufacturing times from acceptance of API to release of the drug product took approximately 30 to 42 days. The COVID–19 pandemic has demonstrated that the flexibility to grant and utilize quotas to produce the formulations and dosage strengths demanded in times of crisis is more important than the availability of large inventories on hand.

Formalization of Subcategories for Manufacturing Quotas and Procurement Quotas

This provision of the final rule is a codification of existing voluntary and cooperative efforts between registrants and DEA that have been in place since 2001 and allows a more accurate calculation of APQ for the United States. The establishment of subcategories of: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling are already being utilized by DEA with full cooperation from all registrants. Therefore, this provision simply updates 21 CFR 1303.03, 1303.04, 1315.06, and 1315.07 to reflect current DEA procedure for the management of quota and will have no economic impact on registrants or DEA.

New Deadlines for Establishing Quotas

The final rule would modify the deadlines for establishing and publishing the APQ, AAN, and procurement and manufacturing quotas, and any adjustments to manufacturing quotas. Due to the expansion of the market and the increase in the number of manufacturers and importers since that deadline was implemented almost 50 years ago, DEA frequently misses the current publishing deadlines for the establishment of the APQ and the AAN of May 1 and the issuing of individual procurement, manufacturing and import quotas deadline of July 1. Applications for import and procurement quota are due April 1, giving DEA only 30 days before the May 1 deadline for publication of the APQ and AAN. Given that DEA has historically missed these deadlines since it must take adequate time to provide a thorough and careful assessment of each application, both DEA and industry have already become accustomed to a delayed publishing schedule. Therefore, this provision is expected to have minimal economic impact as it simply aligns the regulatory deadlines with the current business practices of DEA and industry.

Summary

In summary, only the procurement quota certification requirement and reduction to inventory allowances impose costs. The certification requirement results in a $23,494 annual cost to all manufacturers and an $11,747 annual cost to all distributors for a combined annual cost of $35,241. The reduction to inventory allowances imposes an estimated annual cost of $600,000 on each of the 44 bulk manufacturers registered with DEA, equating to $26.4 million in total annual costs.

Description and Estimate of the Number of Small Entities

This rule has the potential to affect entities registered with DEA as manufacturers, distributors, and importers of controlled substances and list I chemicals. Based on a review of respective representative North American Industry Classification System (NAICS) codes for manufacturers,[17] distributors, and importers,[18] there are the following number of firms: [19]

- 404 'Medicinal and Botanical Manufacturing' (325411)
- 957 'Pharmaceutical Preparation Manufacturing' (325412)
- 6,739 'Drugs and Druggists' Sundries Merchant Wholesalers' (424210)

The U.S. Small Business Administration (SBA) considers a size standard as the largest that a concern can be and still qualify as a small business for Federal government programs. For the most part, size standards are the average annual receipts or the average employment of a firm. The SBA size standards for the three industries are 1,000 employees for Medicinal and Botanical Manufacturing, 1,250 employees for Pharmaceutical Preparation Manufacturing, and 250 employees for Drugs and Druggists' Sundries Merchant Wholesalers.[20]

Comparing the SBA size standards to the U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) detailed data on establishment size by NAICS code for each affected industry, DEA estimates the following number of small entities (and percent of establishments that are small entities) by industry:

- 377 (93.3 percent of total) 'Medicinal and Botanical Manufacturing' (325411);
- 885 (92.5 percent of total) 'Pharmaceutical Preparation Manufacturing' (325412); and
- 6,475 (96.1 percent of total) 'Drugs and Druggists' Sundries Merchant Wholesalers' (424210).

The table below summarizes the calculation for the estimated number of small entities (establishments) above.

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[17] DEA believes 'Pharmaceutical Preparation Manufacturing' (325412) includes 503B outsourcing facilities.

[18] DEA believes 'Drugs and Druggists' Sundries Merchant Wholesalers' (424210) includes both distributors and importers of controlled substances and (human form) list I chemicals.

[19] For the purposes of this analysis, the term ''firm'' is synonymous with ''entities.''

[20] SBA ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes, Effective August 19, 2019.''

Detailed Analysis of Percentage of Entities That Are Small Entities by Industry.

NAICS Description	Firm Size by Average Employees	Firms	Establish-ments	SBA Size Standard	Small Entities	% Small Entities
325411-Medicinal and Botanical Manufacturing	Total	404	439	1,000	377	93.3
	<500	367	376	1,000	367	100
	500-749	4	6	1,000	4	100
	750-999	6	8	1,000	6	100
	1,000-1,499	6	6	1,000	0	0
	1,500-1,999	1	1	1,000	0	0
	2,000-2,499	3	4	1,000	0	0
	2,500-4,999	3	10	1,000	0	0
	5,000+	14	26	1,000	0	0
325412-Pharmaceutical Preparation Manufacturing	Total	957	1,208	1,250	885	92.5
	<500	850	870	1,250	850	100
	500-749	20	31	1,250	20	100
	750-999	10	17	1,250	10	100
	1,000-1,499	10	20	1,250	5	50
	1,500-1,999	8	9	1,250	0	0
	2,000-2,499	4	10	1,250	0	0
	2,500-4,999	19	68	1,250	0	0
	5,000+	36	183	1,250	0	0
424210-Drugs and Druggists' Sundries Merchant Wholesalers	Total	6,739	9,964	250	6,475	96.1
	<100	6,304	6,436	250	6,304	100
	100-149	104	133	250	104	100
	150-199	43	52	250	43	100
	200-299	48	76	250	24	50
	300-399	29	47	250	0	0
	400-499	16	85	250	0	0
	500-749	34	59	250	0	0
	750-999	17	81	250	0	0
	1,000-1,499	15	80	250	0	0
	1,500-1,999	13	28	250	0	0
	2,000-2,499	16	58	250	0	0
	2,500-4,999	32	118	250	0	0
	5,000+	68	2,711	250	0	0

BILLING CODE 4410–09–C

Because DEA registrants frequently hold more than one registration for separate locations, one entity may hold many registrations. DEA estimates the number of affected entities by multiplying the number of DEA registrations in each business activity by its ''firm-to-establishment'' ratio to find the total amount of entities. The firm-to-establishment ratio is calculated by dividing the number of firms in each industry NAICS code by the total number of establishments found in the third and fourth columns of the previous table.[21] DEA analyzed how each provision of the proposed rule will affect DEA registrants, including how many entities each provision will affect, and found that at least one provision of this proposed rule will affect 561 DEA registered entities. A summary of this analysis is detailed in the table below:

[21] For example, the firm-to-establishment ratio for NAICS 325412 is obtained by dividing the 957 total firms in the industry by the 1,208 total establishments in the industry, yielding a ratio of .79.

Summary of DEA Registered Entities Affected by Provision of Proposed Rule

Activity	DEA Registr-ants	Provisions						Affected Entities*
		Inventory Allowance	APQ and AAN Dates	Subcateg-ories	SUPPORT Act	Definit-ions	Quota Cert	
Manufacturer CS, Bulk	44	Yes	Yes	Yes	Yes	Yes	No	40
Manufacturer List I, Bulk		Yes	Yes	Yes	Yes	Yes	No	
Manufacturer CS, Dosage	417	Yes	Yes	Yes	Yes	Yes	Yes	329
Manufacturer List I, Dosage		Yes	Yes	Yes	Yes	Yes	Yes	
Importer List I	35	No	Yes	No	No	Yes	No	24
Distributor CS	143	No	No	No	No	Yes	Yes	97
Distributor List I	104	No	No	No	No	Yes	Yes	71
Total								**561**

*Firm-to-establishment ratios of .92 for bulk manufacturers (NAICS 352411), .79 for dosage-form manufacturers (NAICS 352412), and .68 for distributors and importers (NAICS 424210) were used to calculate the number of affected entities.

After accounting for how many DEA registered entities are affected by each provision, DEA applied the estimated percentage of establishments that are small entities to each respective business activity to estimate the number of affected small entities. DEA estimates that of the 561 affected entities 525 are small entities: 161 distributors, 304 dosage-form manufacturers, 37 bulk manufacturers, and 23 importers. In summary, the percentages of small entities affected are as follows:

- 9.8 percent 'Medicinal and Botanical Manufacturing' (325411);
- 34.4 percent 'Pharmaceutical Preparation Manufacturing' (325412); and
- 2.8 percent 'Drugs and Druggists' Sundries Merchant Wholesalers' (424210).

The table below summarizes the estimated number of small entities, number of affected small entities, and the percentage of small entities affected.

Summary of Industry, SBA Size Standard, and Affected Small Entities.

NAICS Code	NAICS Description	Small Entity Threshold/ SBA Size Standard	Estimated Number of Small Entities	Estimated Number of Affected Small Entities	Percentage of Small Entities Affected
325411	Medicinal and Botanical Manufacturing	1,000	377	37	9.8
325412	Pharmaceutical Preparation Manufacturing	1,250	885	304	34.4
424210	Drugs and Druggists' Sundries Merchant Wholesalers	250	6,475	184*	2.8
Total			**7,737**	**525**	**N/A**

*161 distributors and 23 importers

As described above, the quota certification provision of this final rule is estimated to cost a total of $23,494 to manufacturers annually and a total of $11,747 to distributors annually, or an average cost of $70 ($23,494/334) per affected manufacturer and $71 ($11,747/166) per distributor. Additionally, the reduction to inventory allowances are estimated to impose costs of $600,000 annually on the 44 affected bulk manufacturers that are registered with DEA, 37 of which are small entities. DEA generally uses 30 percent as a ''substantial'' number of affected small entities. The analysis reveals that a non-substantial percentage of small distributor entities (2.8 percent) and

small bulk manufacturer entities (9.8 percent) will be affected while a substantial percentage of small dosage-form manufacturing entities (34.3 percent) will be affected by this rule. DEA generally considers impacts that are greater than three percent of yearly revenue to be a ''significant economic impact'' on an entity. DEA compared the compliance cost of $70 and $71 to the average annual receipts of dosage-form manufacturers and distributors/imports, respectively, for each size range.[22] Additionally, DEA compared the estimated $600,000 per-entity cost attributed to reducing inventory allowances to the average annual receipts of bulk manufacturers for each size range. For even the smallest of entities, the costs calculated above are much less than three percent of yearly revenue and are not significant. The table below summarizes the analysis.

Summary of Analysis.

NAICS Code	NAICS Description	Small Entity Threshold/ SBA Size Standard	Estimated Number of Small Entities	Estimated Number of Affected Small Entities	Percentage of Small Entities Affected	Economic Impact of Compliance
352411	Medicinal and Botanical Manufacturing	1,000	377	37	9.8 (Not Substantial)	Not Significant
325412	Pharmaceutical Preparation Manufacturing	1,250	885	304	38.6 (Substantial)	Not Significant
424210	Drugs and Druggists' Sundries Merchant Wholesalers	250	6,475	184*	2.8 (Not Substantial)	Not Significant

*161 distributors and 23 importers

DEA examined the economic impact of this final rule for each affected industry for various size ranges. Based on the analysis above, and because of these facts, DEA believes this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year and will not significantly or uniquely affect small governments. Therefore, no actions were deemed subject to the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

Paperwork Reduction Act of 1995

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), this action revises existing information collections 1117–0006, 1117–0008, and 1117–0047 and creates one new information collection. DEA is amending its regulations for establishing quotas for United States companies manufacturing schedules I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine and for procurement quota certification and recordkeeping requirements. A person is not required to respond to a collection of information unless it displays a valid OMB control number. DEA has submitted these collection requests to the OMB for review and approval.

A. Collections of Information Associated With the Proposed Rule

1. *Title:* Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

OMB Control Number: 1117–0006.

DEA Form Number: DEA–189.

DEA is formally implementing the use of subcategories to facilitate the issuance of manufacturing quotas and provide a more accurate calculation of the aggregate production quotas for the United States. DEA will be adding the following five subcategories for quota: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling. All types of quota could be requested using the same application and format registrants are accustomed to using in an online form. Manufacturers of schedules I and II controlled substances and list I chemicals will continue to receive manufacturing and procurement quotas appropriate to their manufacturing and inventory requirements, and DEA will retain greater control over the amount of these controlled substances and list I chemicals produced, thereby reducing the amount of inventories at risk of diversion.

DEA estimates the following number of respondents and burden associated with reporting:

- *Number of respondents:* 33.
- *Frequency of response:* Annually/As-needed (26.0303 average).
- *Number of responses:* 859.
- *Burden per response:* 0.5 hour.
- *Total annual hour burden:* 430.

2. *Title:* Application for Procurement Quota for Controlled Substances and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

OMB Control Number: 1117–0008.

DEA Form Number: DEA–250.

DEA is formally implementing the use of subcategories to facilitate the issuance of procurement quotas and provide a more accurate calculation of the aggregate production quotas for the

[22] Small Business Administration, Office of Advocacy ''Table 2—Number of firms, establishments, receipts, employment, and payroll by firm size (in receipts) and industry, 2012.'' *https://www.sba.gov/advocacy/firm-size-data,* accessed 5/24/2018.

United States. DEA is adding the following five subcategories for quota: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling. All types of quota will be requested using the same application and format registrants are accustomed to using in an online form. Manufacturers of schedules I and II controlled substances and list I chemicals will continue to receive manufacturing and procurement quotas appropriate to their manufacturing and inventory requirements, and DEA will retain greater control over the amount of these controlled substances and list I chemicals produced, thereby reducing the amount of inventories at risk of diversion.

DEA estimates the following number of respondents and burden associated with reporting:

- *Number of respondents:* 344.
- *Frequency of response:* Annually/As-needed (8.9128 average).
- *Number of responses:* 3,066.
- *Burden per response:* 0.5 hour.
- *Total annual hour burden:* 1,533.

3. *Title:* Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

OMB Control Number: 1117–0047.

DEA Form Number: DEA–488.

DEA will be formally implementing the use of subcategories to facilitate the issuance of import quotas and provide a more accurate calculation of the assessment of annual needs for the United States. DEA is adding the following five subcategories for quota: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling. All types of quota will be requested using the same application and format registrants are accustomed to using in an online form. Importers of list I chemicals will continue to receive import quotas appropriate to their manufacturing and inventory requirements, and DEA will retain greater control over the amount of these list I chemicals produced, thereby reducing the amount of inventories at risk of diversion.

DEA estimates the following number of respondents and burden associated with reporting:

- *Number of respondents:* 49.
- *Frequency of response:* Annually/As-needed (2.5714 average).
- *Number of responses:* 126.
- *Burden per response:* 0.5 hour.
- *Total annual hour burden:* 63.

4. *Title:* Procurement Quota Certification and Recordkeeping Requirements.

OMB Control Number: 1117–0055.

DEA Form Number: N/A.

This final rule will require all DEA registrants supplying schedules I and II controlled substances or list I chemicals to DEA manufacturers to obtain certification of the manufacturer's procurement quota before completing the transaction. This provision will prevent manufacturers from purchasing active pharmaceutical ingredients from distributors, rather than other manufacturers, without including a quota certification. Current DEA regulations stipulate only that orders to entities registered as importers, manufacturers, or bulk manufacturers must include quota certifications. Manufacturers procuring schedules I and II controlled substances or list I chemicals must maintain a copy of the certification they provide with their order for a period of two years from the date of the certification. Under this final rule, this recordkeeping requirement will apply to certifications included with orders for schedules I and II controlled substances or list I chemicals to all registrants, including distributors.

DEA estimates that distributors fill an average of 3,000 orders to manufacturers per year, which under this final rule, will require 3,000 certification letters to be drafted and retained by manufacturers and reviewed by distributors. The estimated yearly cost of this activity is $35,241. For the purposes of this final rule, DEA estimates the following number of respondents and burden associated with the proposed requirement that procuring manufacturers create and retain copies of schedules I and II controlled substance and list I chemical quota certifications for two years:

- *Number of respondents:* 500 (334 manufacturers and 166 distributors).
- *Frequency of response:* 9 per year.
- *Number of responses:* 3,000.
- *Burden per response:* .25 (minimal).
- *Total annual hour burden:* 750 (minimal).

If you need a copy of the information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

No comments were received on any of the information collections being modified in connection with this final rule. Any comments related this collection of information may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB49/Docket No. DEA–455.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects

21 CFR Part 1303

Administrative practice and procedure, Drug traffic control.

21 CFR Part 1315

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

For the reasons set forth above, DEA is amending 21 CFR parts 1303 and 1315 as follows:

PART 1303—QUOTAS

■ 1. The authority citation for 21 CFR part 1303 continues to read as follows:

Authority: 21 U.S.C. 821, 826, 871(b).

■ 2. Add §§ 1303.03, 1303.04, and 1303.05 to read as follows:

§ 1303.03 Types of quotas.

The three types of quotas are:

(a) Aggregate production quotas, which establish the total quantity of each basic class of schedules I and II controlled substances that may be produced by all manufacturers in a calendar year.

(b) Individual manufacturing quotas, which establish the maximum quantity of each basic class of schedules I and II controlled substances that a registered manufacturer may manufacture during a calendar year. This type of quota is only issued to DEA-registered bulk manufacturers.

(c) Procurement quotas, which establish the maximum quantity of each basic class of schedules I and II controlled substances that a registered manufacturer may procure during a calendar year for the purpose of manufacturing into dosage-forms or other substances.

§ 1303.04 Subcategories of manufacturing and procurement quotas.

The five subcategories of manufacturing and procurement quotas are:

(a) *Quota for commercial sale.* This is a quota for the amount of bulk active pharmaceutical ingredients (API) initially acquired by a registrant for the manufacture of approved schedule I or II controlled substance drug products by the Food and Drug Administration (FDA), and bulk API acquired by outsourcing facilities, manufacturers, etc. This quota category is used to capture bulk API moving from a bulk manufacturer to other registered manufacturers for their commercial manufacturing efforts. This type of quota may only be used to support commercial manufacturing efforts and may not be used to support other manufacturing efforts.

(b) *Quota for transfer.* This is a quota for the amount of material moved upstream from one registrant to another and does not include material captured under procurement quota for commercial sale. Examples include:

(1) Bulk API being transferred back to the original registrant after milling;

(2) Transfer of in-process material or finished dosage-forms for additional manufacturing efforts (coating, beading, encapsulation, and so forth) back to the preceding registrant; and

(3) Return of material after the specified manufacturing activity has been completed or return of rejected material to the upstream manufacturer for destruction or additional processing.

(c) *Quota for product development.* This is a quota for the amount of material needed for product development and validation of manufacturing efforts. This quota is limited to that activity *only* and only for the development efforts noted in the application; it shall not be used or substituted for commercial production or the development of a different product. This quota is issued with the understanding that this material is not intended for commercial use, with the exception of post-FDA approved validation batches. Validation batches shall be noted specifically in an application and shall be considered product development material that will be taken into account for net disposal once a product is FDA-approved for commercial sale. No inventory will be granted for these efforts, nor will replacement quota be considered for destroyed material issued under this quota subcategory.

(d) *Quota for replacement.* This is a type of individual manufacturing quota or procurement quota that is granted to a registrant after the registrant disposes of material that was initially intended for commercial sale, but for some reason was unable to be marketed. This quota is separate and shall not count against a registrant's other issued quota. Replacement quota will be granted on a case-by-case basis. The merits of the request will be determined by the specifics of the registrant's justification and situation. DEA will review the submitted DEA Form 41 or DEA Form 222 documenting the destruction of the controlled substance and evaluate the justification for the destruction to determine if replacement quota is warranted and whether or not the destroyed material is required to meet the legitimate demand of the market. Replacement quota is intended to replace material from the current quota year and not a means to replace disposed samples, analytical samples, product development material, or inventory acquired under previous quota years.

(e) *Quota for packaging/repackaging and labeling/relabeling.* This is the quota for the amount of material moved to a registrant to undergo packaging and labeling activities. This quota is limited to that activity *only* and only for the packaging/repackaging and labeling/relabeling noted in the application; it may not be used or substituted for commercial production. Packaging/repackaging and labeling/relabeling quota is intended for tracking of schedules I and II controlled substances as they undergo packaging/labeling activities; however, packaging/repackaging and labeling/relabeling quotas shall not be counted against the aggregate production quotas.

§ 1303.05 Estimation of Diversion.

(a) In establishing any quota under the sections in this part for a covered controlled substance, the Administrator shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.

(b) In estimating diversion under the sections in this part, the Administrator:

(1) Shall consider information the Administrator, in consultation with the Secretary of Health and Human Services, determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and

(2) May take into consideration whatever other sources of information the Administrator determines reliable.

(c) After estimating the amount of diversion of a covered controlled substance, the Administrator shall make appropriate quota reductions, as determined by the Administrator, from the quota the Administrator would have otherwise established had such diversion not been considered.

(d) For purposes of this Part, the term ''covered controlled substances'' refers to fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone.

■ 3. Revise the undesignated center heading ''Aggregate Production and Procurement Quotas'' to read as ''Aggregate Production Quotas''.

■ 4. Amend § 1303.11 by:

■ a. Adding a sentence to the end of paragraph (a);

■ b. Removing the date ''May 1'' in the first sentence of paragraph (c) and adding in its place ''September 1''; and

■ c. Adding paragraph (d).

The revisions to read as follows:

§ 1303.11 Aggregate production quotas.

(a) * * * The Administrator may establish an aggregate production quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule I or II controlled substance, if he determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance.

* * * * *

(d) For any year for which the approved aggregate production quota for a covered controlled substance, as defined in § 1303.05(d), is higher than the approved aggregate production quota for the covered controlled substance for the previous year, the Administrator, in consultation with the Secretary of Health and Human Services, shall include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

■ 5. Add an undesignated center heading before § 1303.15 to read as follows:

* * * * *

Procurement Quotas

* * * * *

§ 1303.12 [Redesignated as § 1303.15]

■ 6. Redesignate § 1303.12 as § 1303.15 and add and reserve a new § 1303.12.

■ 7. Amend newly redesignated 1303.15 § by:

■ a. Adding a sentence to the end of paragraph (a);

■ b. Revising the first sentence in paragraph (b);

■ c. Removing ''July'' in paragraph (c) introductory text and adding in its place ''December''; and

■ d. In paragraph (f), removing the words ''manufacturer'' and ''bulk manufacturer'' and adding in their place ''registrant'', and removing ''Manufacturers'' and adding in its place ''A registrant''.

The revision to read as follows:

§ 1303.15 Procurement quotas.

(a) * * * The Administrator may establish a procurement quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule I or II controlled substance, if they determine it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance.

(b) Any person who is registered to manufacture controlled substances listed in any schedule and who desires to use during the next calendar year any basic class of controlled substances listed in schedule I or II (except raw opium being imported by the registrant pursuant to an import permit) for purposes of manufacturing, shall apply on DEA Form 250 for procurement quota and shall state separately for each subcategory, as defined in 21 CFR 1303.04, each quantity of such basic class. * * *

* * * * *

■ 8. Add § 1303.16 to read as follows:

§ 1303.16 Inventory allowance for procurement quotas.

(a) For the purpose of determining procurement quotas pursuant to § 1303.15, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory:

(1) Except as provided in paragraph (a)(3) of this section, for current manufacturers, 35 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) Except as provided in paragraph (a)(4) of this section, for new manufacturers, 35 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(3) For current liquid injectable dosage-form manufacturers, 50 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or

(4) For new liquid injectable dosage-form manufacturers, 50 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) Except as provided in paragraph (c) of this section, during each calendar year, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a basic class not exceeding 50 percent of his estimated net disposal of that class for that year, as determined at the time their quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 50 percent of their estimated net disposal, their quota for that class is automatically suspended and shall remain suspended until his inventory is less than 45 percent of their estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 50 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) For liquid injectable dosage-forms, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a basic class not exceeding 65 percent of their estimated net disposal of that class for that year during each calendar year, as determined at the time their quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 65 percent of their estimated net disposal, their quota for that class is automatically suspended and shall remain suspended until their inventory is less than 60 percent of his estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 65 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(d) Except as provided in paragraph (e) of this section, if, during a calendar year, a registrant has procured the entire quantity of a basic class allocated to him under an individual procurement quota, and their inventory of that class is less than 25 percent of his estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1303.15(d), increase the quota of such registrant sufficiently to allow restoration of the inventory to 35 percent of the estimated net disposal for that year.

(e) For liquid injectable dosage-forms, if, during a calendar year, a registrant has procured the entire quantity of a basic class allocated to them under an individual procurement quota, and their inventory of that class is less than 40 percent of their estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1303.15(d), increase the quota of such registrant sufficiently to allow restoration of the inventory to 50 percent of the estimated net disposal for that year.

■ 9. Add § 1303.17 to read as follows:

§ 1303.17 Abandonment of procurement quota.

Any manufacturer assigned a procurement quota for any basic class of controlled substance listed in schedule I or II pursuant to § 1303.12 may at any time abandon their right to manufacture all or any part of such quota by filing a notice of such abandonment with the UN Reporting and Quota Section, Diversion Control Division, Drug Enforcement Administration in the online Quota Management System. The Administrator may, in their discretion, allocate such amount among the other manufacturers in proportion to their respective quotas.

■ 10. In § 1303.21 amend paragraph (a) by removing the date ''July 1'' in the first sentence and adding in its place ''December 1'' and adding a new second sentence to read as follows

§ 1303.21 Individual manufacturing quotas.

(a) * * * The Administrator may establish an individual manufacturing quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule I or II controlled substance, if they determine it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. * * *

* * * * *

■ 10. Amend § 1303.22 by revising the first sentence of the introductory text to read as follows:

§ 1303.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture any basic class of controlled substance listed in schedule I or II and who desires to manufacture a quantity of such class shall apply on DEA Form 189 for a manufacturing quota and shall state separately for each subcategory, as defined in § 1303.04, each quantity of such class. * * *

* * * * *

§ 1303.23 Procedure for applying for individual manufacturing quotas.

■ 11. In § 1303.23, amend paragraph (c) by removing the date ''March 1'' in the first sentence and adding in its place ''July 1''.

■ 12. Revise § 1303.24 to read as follows:

§ 1303.24 Inventory allowance for individual manufacturing quotas.

(a) For the purpose of determining individual manufacturing quotas pursuant to § 1303.23, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory equal to:

(1) For current manufacturers, 40 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 40 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) During each calendar year, each registered manufacturer shall be allowed to maintain an inventory of a basic class not exceeding 55 percent of their estimated net disposal of that class for that year, as determined at the time their quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 55 percent of their estimated net disposal, their quota for that class is automatically suspended and shall remain suspended until their inventory is less than 50 percent of their estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 55 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a basic class allocated to them under an individual manufacturing quota, and their inventory of that class is less than 30 percent of their estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1303.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 40 percent of the estimated net disposal for that year.

■ 13. Amend § 1303.27 by revising the section heading and the first sentence to read as follows:

§ 1303.27 Abandonment of quota for Individual Manufacturing Quota.

Any manufacturer assigned an individual manufacturing quota for any basic class of controlled substance listed in schedule I or II pursuant to § 1303.23 may at any time abandon their right to manufacture all or any part of such quota by filing a notice of such abandonment with the UN Reporting and Quota Section, Diversion Control Division, Drug Enforcement Administration in the online Quota Management System. * * *

PART 1315—IMPORTATION AND PRODUCTION QUOTAS FOR EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE

■ 14. The authority citation for part 1315 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 826, 871(b), 952.

■ 15. Add § 1315.06 to read as follows:

§ 1315.06 Assessment of Annual Needs; Types of quotas.

The four types of quotas are:

(a) Assessment of annual needs, which establishes the total quantity of ephedrine, pseudoephedrine, and phenylpropanolamine necessary to be manufactured and imported by all manufacturers and importers in a calendar year.

(b) Individual manufacturing quotas, which establish the maximum quantity of ephedrine, pseudoephedrine, and phenylpropanolamine that a registered manufacturer may manufacture during a calendar year. This type of quota is only issued to DEA-registered bulk manufacturers.

(c) Procurement quotas, which establish the maximum quantity of ephedrine, pseudoephedrine, and phenylpropanolamine that a registered manufacturer may procure during a calendar year for the purpose of manufacturing into dosage-forms or other substances.

(d) Import quotas, which establish the maximum quantity of ephedrine, pseudoephedrine, and phenylpropanolamine that a registered importer may import during the calendar year for distribution to their DEA-registered customers.

■ 16. Add § 1315.07 to read as follows:

§ 1315.07 Subcategories of manufacturing and procurement quota.

The five subcategories are:

(a) Quota for Commercial Sale is a quota for the amount of bulk active pharmaceutical ingredients (API) initially acquired by a registrant for the manufacture of ephedrine, pseudoephedrine, and phenylpropanolamine products and bulk API acquired by outsourcing facilities, manufacturers, etc. This type of quota shall only be used to support commercial manufacturing efforts and shall not be used to support other manufacturing efforts.

(b) Quota for Transfer is a quota for the amount of material moved from one registrant to another and does not include material captured under procurement quota for commercial sale. Examples include: 1. Bulk API being transferred back to the original registrant after milling; 2. Transfer of in-process material or finished dosage-forms for additional manufacturing efforts (coating, beading, encapsulation, and so forth) back to the preceding registrant; and 3. Return of material after the specified manufacturing activity has been completed.

(c) Quota for Product Development is a quota for the amount of material needed for product development and validation manufacturing efforts. This quota is limited to that activity *only* and only for the development efforts noted in the application; it shall not be used or substituted for commercial production or the development of a different product. This quota is issued with the understanding that this material is not intended for commercial use, with the exception of FDA-approved or OTC Monograph validation batches. Validation batches shall be noted specifically in an application and shall be considered product development material that will be taken into account once a product is FDA-approved for commercial sale. No inventory shall be granted for these efforts, nor shall replacement quota be considered for destroyed material issued under this quota subcategory.

(d) Quota for Replacement is a type of individual manufacturing quota or procurement quota that is granted to a registrant after the registrant disposes of material that was initially intended for commercial sale, but for some reason was unable to be marketed. This quota is separate and shall not count against a registrant's other issued quota. Replacement quota will be granted on a case by case basis. The merits of the request shall be determined by the registrant's justification. Replacement quota is intended to replace material from the current quota year and shall not be used to replace disposed samples, analytical samples, product development material or inventory acquired under previous quota years.

(e) Quota for Packaging/Repackaging and Labeling/Relabeling is quota for the amount of material moved to a registrant to undergo packaging and labeling activities. This quota is limited to that activity *only* and only for the packaging/repackaging and labeling/relabeling noted in the application; it shall not be used or substituted for commercial

production or the packaging of a different product.

§ 1315.11 Assessment of annual needs.

■ 17. In § 1315.11, amend paragraph (c) by removing the date ''May 1'' in the first sentence and adding in its place the date ''September 1''.

§ 1315.21 Individual manufacturing quotas.

■ 18. Amend § 1315.21 by removing the date ''July 1'' in the first sentence and adding in its place the date ''December 1''.

■ 19. Amend § 1315.22 by revising the first sentence of the introductory text to read as follows:

§ 1315.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine and who desires to manufacture a quantity of the chemical must apply on DEA Form 189 for a manufacturing quota for the quantity of the chemical and shall state separately for each subcategory, as defined in § 1315.07, each quantity of such chemical. * * *

* * * * *

§ 1315.23 Procedure for fixing individual manufacturing quotas.

■ 20. In § 1315.23, amend paragraph (c) by removing the date ''March 1'' in the first sentence and adding in its place the date ''July 1''.

■ 21. Revise § 1315.24 to read as follows:

§ 1315.24 Inventory allowance for individual manufacturing quotas.

(a) For the purpose of determining individual manufacturing quotas pursuant to § 1315.23, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory:

(1) For current manufacturers, 40 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 40 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) During each calendar year, each registered manufacturer receiving a manufacturing quota shall be allowed to maintain an inventory of a chemical not exceeding 55 percent of their estimated net disposal of that chemical for that year, as determined at the time his quota for that year was determined. At any time the inventory of a chemical held by a manufacturer exceeds 55 percent of their estimated net disposal, their quota for that chemical is automatically suspended and shall remain suspended until their inventory is less than 50 percent of his estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 55 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a chemical allocated to them under an individual manufacturing quota, and their inventory of that chemical is less than 30 percent of his estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1315.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 40 percent of the estimated net disposal for that year.

■ 22. Amend § 1315.27 by revising the first sentence to read as follows:

§ 1315.27 Abandonment of individual manufacturing quota.

Any manufacturer assigned an individual manufacturing quota for a chemical pursuant to § 1315.23 may at any time abandon their right to manufacture all or any part of such quota by filing a notice of such abandonment with the UN Reporting and Quota Section, Diversion Control Division, Drug Enforcement Administration in the online Quota Management System. * * *

■ 23. Add § 1315.31 to read as follows:

§ 1315.31 Inventory allowance for procurement quotas.

(a) For the purpose of determining procurement quotas pursuant to § 1315.32, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory:

(1) Except as provided in paragraph (a)(3) of this section, for current manufacturers, 35 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) Except as provided in paragraph (a)(4) of this section, for new manufacturers, 35 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(3) For current liquid injectable dosage-form manufacturers, 50 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(4) For new liquid injectable dosage-form manufacturers, 50 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) Except as provided in paragraph (c) of this section, during each calendar year, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a chemical not exceeding 50 percent of his estimated net disposal of that chemical for that year, as determined at the time his quota for that year was determined. At any time the inventory of a chemical held by a manufacturer exceeds 50 percent of his estimated net disposal, his quota for that chemical is automatically suspended and shall remain suspended until his inventory is less than 45 percent of his estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 50 percent of his estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) For liquid-injectable dosage-forms, during each calendar year, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a chemical not exceeding 65 percent of his estimated net disposal of that chemical for that year, as determined at the time his quota for that year was determined. At any time the inventory of a chemical held by a manufacturer exceeds 65 percent of his estimated net disposal, his quota for that chemical is automatically suspended and shall remain suspended until his inventory is less than 60 percent of his estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 65 percent of his estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(d) If, during a calendar year, a registrant has procured the entire quantity of a chemical allocated to him under an individual procurement quota, and his inventory of that chemical is less than 25 percent of his estimated net disposal of that class for that year, the

Administrator may, upon application pursuant to § 1315.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 35 percent of the estimated net disposal for that year.

(e) For liquid-injectable dosage-forms, if, during a calendar year, a registrant has procured the entire quantity of a chemical allocated to him under an individual procurement quota, and his inventory of that chemical is less than 40 percent of his estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1315.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 50 percent of the estimated net disposal for that year.

■ 24. Amend § 1315.32 by:

■ a. Revising the first sentence in paragraph (a);

■ b. Removing the date ''July 1'' in the introductory text of paragraph (f) and adding in its place the date ''December 1'';

■ c. Removing ''manufacturer or importer'' in paragraph (h) and adding in its place ''registrant''.

The revision to read as follows:

§ 1315.32 Obtaining a procurement quota.

(a) Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine, or whose requirement of registration is waived pursuant to § 1309.24 of this chapter, and who desires to use during the next calendar year any ephedrine, pseudoephedrine, or phenylpropanolamine for purposes of manufacturing (including repackaging or relabeling), must apply on DEA Form 250 for a procurement quota for the chemical and shall state separately for each subcategory, as defined in 21 CFR 1315.07, each quantity of such chemical. * * *

* * * * *

§ 1315.34 Obtaining an import quota.

■ 25. In § 1315.34 amend paragraph (f) by removing the date ''July 1'' and adding, in its place, the date ''December 1''.

■ 26. Add § 1315.37 to read as follows:

§ 1315.37 Abandonment of procurement quota.

Any manufacturer assigned a procurement quota for a chemical pursuant to § 1315.23 may at any time abandon his right to manufacture all or any part of such quota by filing a notice of such abandonment with the UN Reporting and Quota Section, Diversion Control Division, Drug Enforcement Administration in the online Quota Management System. The Administrator may, in his discretion, allocate the amount among the other manufacturers in proportion to their respective quotas.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 28, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–18885 Filed 8–30–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 310

[Docket ID: DoD–2023–OS–0076]

RIN 0790–AL68

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary of Defense, Department of Defense (DoD).

ACTION: Technical amendment.

SUMMARY: The DoD is amending this part to correct an error in the Privacy Act exemption rule associated with the Privacy Act system of records DoD–0007, ''Defense Reasonable Accommodation and Assistive Technology Records.''

DATES: The rule will be effective on August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Rahwa Keleta, *OSD.DPCLTD@mail.mil,* (703) 571–0070.

SUPPLEMENTARY INFORMATION: The Privacy Act permits Federal agencies to exempt eligible records in a system of records from certain provisions of the Act, including the provisions providing individuals with a right to request access to and amendment of their own records and accountings of disclosures of such records. If an agency intends to exempt a particular system of records, it must first go through the rulemaking process to provide public notice and an opportunity to comment on the exemption.

DoD is amending 32 CFR 310.13(e)(6) to correct an error in the Privacy Act exemption rule associated with the Privacy Act system of records notice DoD–0007, ''Defense Reasonable Accommodation and Assistive Technology Records.'' Section 310.13(e)(6) erroneously claims an exemption for this system of records from 5 U.S.C. 552a(c)(4), which generally requires the agency maintaining the system of records to inform recipients with whom it has shared a record if later the record was corrected or disputed pursuant to the requirements of the Privacy Act. DoD's inclusion of subsection 552a(c)(4) was an error and DoD is removing it from the exemption rule as well as the DoD–0007 system of records notice, which is being modified in a notice published concurrently in today's issue of the **Federal Register**.

Regulatory Analysis

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this rule is not a significant regulatory action under these Executive Orders.

Congressional Review Act (5 U.S.C. 804(2))

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. DoD 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. A major rule may take effect no earlier than 60 calendar days after Congress receives the rule report or the rule is published in the **Federal**

Register, whichever is later. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Section 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates may result in the expenditure by State, local and tribal governments in the aggregate, or by the private sector, in any one year of $100 million in 1995 dollars, updated annually for inflation. This rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601 et seq.)

The ATSD(PCLT) has certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule is concerned only with the administration of Privacy Act systems of records within the DoD. Therefore, the Regulatory Flexibility Act, as amended, does not require DoD to prepare a regulatory flexibility analysis.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 501 et seq.)

The Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) was enacted to minimize the paperwork burden for individuals; small businesses; educational and nonprofit institutions; Federal contractors; State, local and tribal governments; and other persons resulting from the collection of information by or for the Federal Government. The Act requires agencies obtain approval from the Office of Management and Budget before using identical questions to collect information from ten or more persons. This rule does not impose reporting or recordkeeping requirements on the public.

Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial effect on State and local governments.

Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments''

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct compliance costs on one or more Indian tribes, preempts tribal law, or affects the distribution of power and responsibilities between the Federal government and Indian tribes. This rule will not have a substantial effect on Indian tribal governments.

List of Subjects in 32 CFR Part 310

Privacy.

Accordingly, 32 CFR part 310 is amended as follows:

PART 310—PROTECTION OF PRIVACY AND ACCESS TO AND AMENDMENT OF INDIVIDUAL RECORDS UNDER THE PRIVACY ACT OF 1974

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 5 U.S.C. 552a.

§ 310.13 [Amended]

■ 2. Section § 310.13 is amended by:
■ a. Removing the first ''and (4)'' from paragraph (e)(6)(i).
■ b. Removing ''(c)(4),'' from the title of paragraph (e)(6)(iii)(A).

Dated: August 24, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18686 Filed 8–30–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2023–0713]

Special Local Regulation; 35th Annual Glass City Regatta ''Formerly Known as Frogtown Race Regatta''

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for the 35th Annual Glass City Regatta ''Formerly known as Frogtown Race Regatta'' on September 23, 2023. This special local regulation is necessary to safely control vessel movement in the vicinity of the race and provide for the safety of the general boating public and commercial shipping. During this enforcement period, no person or vessel may enter the regulated area without the permission of the Coast Guard Patrol Commander (PATCOM).

DATES: The regulation in 33 CFR 100.911 will be enforced from 7 a.m. through 5 p.m. on September 23, 2023.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email MST1 Luke Harp, Marine Safety Unit Toledo, U.S. Coast Guard; telephone 419–418–6040, email *Thomas.L.Harp@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a special local regulation found in 33 CFR 100.911 for the 35th Annual Glass City Regatta ''Formerly known as Frogtown Race Regatta'' from 7 a.m. through 5 p.m. on September 23, 2023. This notice of enforcement is necessary to safely control vessel movement in the vicinity of the race and provide for the safety of the general boating public and commercial shipping. This notice of enforcement applies to all U.S. navigable waters of the Maumee River from the I–280 Bridge south to the I–75 bridge.

To ensure the safety of the spectators and participating vessels, the Coast Guard will patrol the race area under the direction of a designated Coast Guard Patrol Commander (PATCOM). Vessel desiring to transit the regulated area may do so only with prior approval of the PATCOM and when so directed by that officer. The PATCOM may be contacted on Channel 16 (156.8 MHZ) by the call sign ''Coast Guard Patrol Commander.'' Vessels permitted to transit the regulated area will operate at no wake speed and in a manner which will not endanger participants in the event or any other craft. The rules contained above shall not apply to participants in the event or vessels of the patrol operating in the performance of their assigned duties.

This notice of enforcement is issued under the authority of 33 CFR 100.911 and 5 U.S.C. 552(a). If the District Commander, Captain of the Port or PATCOM determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: August 24, 2023.

Richard P. Armstrong,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2023–18805 Filed 8–30–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2023–0706]

RIN 1625–AA00

Safety Zone; Upper Mississippi River MM 476, Davenport, IA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters in the Upper Mississippi River at Mile Marker (MM) 476.6. The safety zone is needed to protect personnel, vessels, and the marine environment from all potential hazards associated with the power line crossing project. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or a designated representative.

DATES: This rule is effective without actual notice from August 31, 2023 through September 11, 2023. For the purposes of enforcement, actual notice will be used from August 28, 2023 until August 31, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0706 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email MSTC Nathaniel Dibley, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2560, email *Nathaniel.D.Dibley@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because potential hazards created by the power line crossing over the Upper Mississippi River and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. It is impracticable to publish an NPRM because we must establish this safety zone by August 28, 2023.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the power line crossing starting August 28, 2023.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Upper Mississippi (COTP) has determined that potential hazards associated with the power line crossing starting August 28, 2023, will be a safety concern for anyone operating or transiting within the Upper Mississippi River from MM 476–477. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the power line crossing is being conducted.

IV. Discussion of the Rule

This rule establishes a safety zone during an power line crossing project over the Upper Mississippi River on August 28, 2023 through September 11, 2023. The safety zone will cover all navigable waters from MM 476–477. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the power line crosses the Upper Mississippi River. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in the size of the safety zone as conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB), as appropriate.

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, and we discuss First Amendment rights of protestors.

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). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on a safety zone located on the Upper Mississippi River MM 476–477 near Davenport, IA. The safety zone will be active only while work associated with the power line crossing is being conducted, from August 28, 2023, until September 11, 2023.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this 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 safety zone 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 call or email 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 will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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 Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone encompassing the width of the Upper Mississippi River from MM 476 to MM 477. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0706 to read as follows:

§ 165.T08–0706 Safety Zone; Upper Mississippi River, Mile Markers 476–477, Davenport, IA.

(a) *Location.* The following area is a safety zone: all navigable waters within the Upper Mississippi River, Mile Markers (MM) 476–477.

(b) *Enforcement period.* This section is subject to enforcement from August 28, 2023 through September 11, 2023.

(c) *Regulations.* (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into the safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size or scope of the safety zone as ice or flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB) as appropriate.

Dated: August 28, 2023.

D.J. Every,

Commander, U.S. Coast Guard, Acting Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2023–18926 Filed 8–29–23; 11:15 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0606]

RIN 1625–AA00

Safety Zone; Swim for Alligator Lighthouse, Islamorada, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on

certain navigable waters of the Atlantic Ocean near Islamorada, Florida during the Swim for Alligator Lighthouse, open water swim event. A safety zone for recurring marine events exists; however, for this year's event the date has changed. The safety zone is necessary to ensure the safety of event participants and spectators. Persons and non-participant vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port (COTP) Key West or a designated representative.

DATES: This rule is effective from 7:30 a.m. until 4 p.m., on September 9, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0606 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Hailye Wilson, Chief, Waterways Management Division, Sector Key West, FL U.S. Coast Guard; telephone 305–292–8768, email *Hailye.m.wilson@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. The Coast Guard has an existing safety zone for this recurring marine event at 33 CFR 165.786, Table to § 165.786, Item No. 9.1; however, the existing regulation only covers the event when it is scheduled on the third Saturday of September. The primary justification for this action is that the Coast Guard received final details of the event without sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. It would be impracticable and contrary to the public interest to delay promulgating this rule, as it is necessary to protect the safety of participants, spectators, the public, and vessels transiting in the area.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because the event is taking place on September 9, 2023, and immediate action is needed to respond to the potential safety hazards associated with this event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority in 46 U.S.C. 70034. The Captain of the Port Key West (COTP) has determined that potential hazards associated with this open water swim event will be a safety concern for persons and vessels in the safey zone. This rule is needed to ensure the safety of the event participants, the general public, vessels and the marine environment in the navigable waters within the safety zone during the Swim for Alligator Lighthouse open water swim event.

IV. Discussion of the Rule

This rule establishes a safety zone on September 9, 2023 for a period of 8.5 hours, from 7:30 a.m. to 4:00 p.m. The safety zone will cover all waters of the Atlantic Ocean, between Amara Cay, and Alligator Lighthouse, beginning at a point Latitude 24°54.82′ N, longitude 080°38.03′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to latitude 24°51.07′ N, longitude 080°37.14′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to point of origin at latitude 24°54.82′ N, longitude 080°38.03′ W. The event course begins and ends at Amara Cay Resort in Islamorada, Florida, and extends through Hawks Channel, with a turnaround at Alligator Lighthouse. Approximately 500 swimmers with kayak escorts and eight safety vessels are anticipated to participate in the event. The size and duration of the safety zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the open water swim. Persons and non-participant vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone without obtaining permission from the COTP Key West or a designated representative. If authorization to enter, transit through, anchor in, or remain within the safety zone is granted by the COTP Key West or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP Key West or a designated representative. The Coast Guard will provide notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners, or by on-scene designated representatives.

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, and we discuss First Amendment rights of protestors.

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). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration and available exceptions to the enforcement of the safety zone. The regulated area will impact small designated areas of the Atlantic Ocean between Islamorada, Florida, and the Alligator Lighthouse for only 8.5 hours and thus is limited in time and scope. Furthermore, the rule will allow vessels to seek permission to enter the safety zone. Non-participant persons and vessels may enter, transit through, anchor in, or remain within the regulated area during the enforcement periods if authorized by the COTP or a designated representative. Vessels not able to enter, transit through, anchor in, or remain within the regulated area without authorization from the COTP or a designated representative may operate in the surrounding areas during the 8.5 hour enforcement period. The Coast Guard will issue a Local Notice to Mariners and a Broadcast Notice to Mariners, allowing mariners to make alternative plans or seek permission to transit the safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this 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 safety zone 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 call or email 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 will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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 Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only 8.5 hours that will prohibit entry into the area being used by swimmers and safety craft for the Alligator Lighthouse swim. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T07–0606 to read as follows:

§ 165.T07–0606 Safety Zone; Swim for Alligator Lighthouse, Islamorada, FL.

(a) *Location.* The following regulated area is a safety zone: All waters of the Atlantic Ocean beginning at a point Latitude 24°54.82′ N, longitude 080°38.03′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to latitude 24°51.07′ N, longitude 080°37.14′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to point of origin at latitude 24°54.82′ N, longitude 080°38.03′ W. The event course begins and ends at Amara Cay Resort in Islamorada, Florida, extending through Hawks Channel with a turnaround point at Alligator Lighthouse. All coordinates are North American Datum 1983.

(b) *Definition.* As used in this section, the term ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Key West (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the COTP Key West or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the COTP Key West by telephone at (305) 292–8772, or a designated representative via VHF–FM radio on channel 16 to request authorization. If authorization is

granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP Key West or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast Notice to Mariners via VHF–FM channel 16, or the COTP's designated representative.

(d) *Enforcement period.* This rule will be enforced from 7:30 a.m. until 4:00 p.m., on September 9, 2023.

Dated: August 22, 2023.

J. Ingram,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2023–18641 Filed 8–30–23; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0618; FRL–9242–03–R4]

Air Plan Approval; North Carolina; Volatile Organic Compound Regulations; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) published a final rule that appeared in the **Federal Register** on August 4, 2023, titled ''Air Plan Approval; North Carolina; Volatile Organic Compound Regulations.'' The document approved revisions to the North Carolina State Implementation Plan concerning several updates to the North Carolina Department of Environmental Quality's air regulations which apply to sources that emit volatile organic compounds. EPA approved those changes pursuant to the Clean Air Act. An error in the instructions amending the Code of Federal Regulations (CFR) in the document is identified and corrected in this action. This correction does not change any final action taken by EPA in the August 4, 2023, final rule.

DATES: Effective September 8, 2023.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2021–0618. All documents in the docket are listed on the *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 if at all possible, 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: Sarah LaRocca, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Ms. LaRocca can be reached via electronic mail at *larocca.sarah@epa.gov* or via telephone at (404) 562–8994.

SUPPLEMENTARY INFORMATION: EPA published a final rule in the **Federal Register** on August 4, 2023 (88 FR 51713), titled ''Air Plan Approval; North Carolina; Volatile Organic Compound Regulations.'' The final rule approved changes to the following regulations in North Carolina's SIP: 15A North Carolina Administrative Code Subchapter 02D, Rules .0901, *Definitions;* .0902, *Applicability;* .0903, *Recordkeeping: Reporting: Monitoring;* .0906, *Circumvention;* .0909, *Compliance Schedules for Sources in Ozone Nonattainment and Maintenance Areas;* .0912, *General Provisions on Test Methods and Procedures;* .0918, *Can Coating;* .0919, *Coil Coating;* .0922, *Metal Furniture Coatings;* .0923, *Surface Coating of Large Appliance Parts;* .0924, *Magnet Wire Coating;* .0925, *Petroleum Liquid Storage in Fixed Roof Tanks;* .0928, *Gasoline Service Stations Stage 1;* .0930, *Solvent Metal Cleaning;* .0931, *Cutback Asphalt;* .0933, *Petroleum Liquid Storage in External Floating Roof Tanks;* .0935, *Factory Surface Coating of Flat Wood Paneling;* .0937, *Manufacture of Pneumatic Rubber Tires;* .0943, *Synthetic Organic Chemical and Polymer Manufacturing;* .0944, *Manufacture of Polyethylene: Polypropylene and Polystyrene;* .0945 *Petroleum Dry Cleaning;* .0947, *Manufacture of Synthesized Pharmaceutical Products;* .0948, *VOC Emissions from Transfer Operations;* .0949, *Storage of Miscellaneous Volatile Organic Compounds;* .0951, *RACT For Sources of Volatile Organic Compounds;* .0955, *Thread Bonding Manufacturing;* .0956, *Glass Christmas Ornament Manufacturing;* .0957, *Commercial Bakeries;* .0961, *Offset Lithographic Printing and Letterpress Printing;* .0962, *Industrial Cleaning Solvents;* .0963, *Fiberglass Boat Manufacturing Materials;* .0964, *Miscellaneous Industrial Adhesives;* .0965, *Flexible Package Printing;* .0966, *Paper, Film and Foil Coatings;* .0967, *Miscellaneous Metal and Plastic Parts Coatings;* and .0968, *Automobile and Light Duty Truck Assembly Coatings.* However, the **Federal Register** document contained an error in the instructions regarding amendments to the table titled ''EPA-Approved North Carolina Regulations'' found at 40 CFR 52.1770(c)(1). *See* 88 FR 51715. In the instructions, EPA inadvertently referred to the table entries to be amended as ''Section .0901,'' ''Section .0902,'' ''Section .0903,'' ''Section .0906,'' ''Section .0909,'' ''Section .0912,'' ''Section .0918,'' ''Section .0919,'' ''Section .0922,'' ''Section .0923,'' ''Section .0924,'' ''Section .0925,'' ''Section .0928,'' ''Section .0930,'' ''Section .0931,'' ''Section .0933,'' ''Section .0935,'' ''Section .0937,'' ''Section .0943,'' ''Section .0944,'' ''Section .0945,'' ''Section .0947,'' ''Section .0948,'' ''Section .0949,'' ''Section .0951,'' ''Section .0955,'' ''Section .0956,'' ''Section .0957,'' ''Section .0961,'' ''Section .0962,'' ''Section .0963,'' ''Section .0964,'' ''Section .0965,'' ''Section .0966,'' ''Section .0967,'' and ''Section .0968'' instead of ''Rule .0901,'' ''Rule .0902,'' ''Rule .0903,'' ''Rule .0906,'' ''Rule .0909,'' ''Rule .0912,'' ''Rule .0918,'' ''Rule .0919,'' ''Rule .0922,'' ''Rule .0923,'' ''Rule .0924,'' ''Rule .0925,'' ''Rule .0928,'' ''Rule .0930,'' ''Rule .0931,'' ''Rule .0933,'' ''Rule .0935,'' ''Rule .0937,'' ''Rule .0943,'' ''Rule .0944,'' ''Rule .0945,'' ''Rule .0947,'' ''Rule .0948,'' ''Rule .0949,'' ''Rule .0951,'' ''Rule .0955,'' ''Rule .0956,'' ''Rule .0957,'' ''Rule .0961,'' ''Rule .0962,'' ''Rule .0963,'' ''Rule .0964,'' ''Rule .0965,'' ''Rule .0966,'' ''Rule .0967,'' and ''Rule .0968'' and therefore inadvertently sought to replace, rather than revise, those entries. EPA is now correcting that error.

Correction

§ 52.1770 [Corrected]

■ In FR Doc. 2023–16600, published at 88 FR 51713 in the issue of August 4, 2023, on page 51715, in the second and third columns, amendatory instruction 2

for § 52.1770 is corrected to read as follows:

■ 2. In § 52.1770, amend the table in paragraph (c)(1) by revising the entries for ''Rule .0901,'' ''Rule .0902,'' ''Rule .0903,'' ''Rule .0906,'' ''Rule .0909,'' ''Rule .0912,'' ''Rule .0918,'' ''Rule .0919,'' ''Rule .0922,'' ''Rule .0923,'' ''Rule .0924,'' ''Rule .0925,'' ''Rule .0928,'' ''Rule .0930,'' ''Rule .0931,'' ''Rule .0933,'' ''Rule .0935,'' ''Rule .0937,'' ''Rule .0943,'' ''Rule .0944,'' ''Rule .0945,'' ''Rule .0947,'' ''Rule .0948,'' ''Rule .0949,'' ''Rule .0951,'' ''Rule .0955,'' ''Rule .0956,'' ''Rule .0957,'' ''Rule .0961,'' ''Rule .0962,'' ''Rule .0963,'' ''Rule .0964,'' ''Rule .0965,'' ''Rule .0966,'' ''Rule .0967,'' and ''Rule .0968'' to read as follows:

Dated: August 25, 2023.

Carol Kemker,

Acting Regional Administrator, Region 4.

[FR Doc. 2023–18708 Filed 8–30–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0406; FRL–10991–03–R4]

Air Plan Approval; North Carolina; Bulk Gasoline Plants, Terminals Vapor Recovery Systems; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) published a final rule in the **Federal Register** on August 9, 2023, titled ''Air Plan Approval; North Carolina; Bulk Gasoline Plants, Terminals Vapor Recovery Systems.'' The document approved revisions to the North Carolina State Implementation Plan (SIP) concerning changes to the North Carolina Department of Environmental Quality's air regulations regarding bulk gasoline terminals and plants, gasoline cargo tanks and vapor collection systems, and leak tightness and vapor leak requirements. EPA approved those changes pursuant to the Clean Air Act. An error in the instructions amending the Code of Federal Regulations (CFR) in the document is identified and corrected in this action. This correction does not change any final action taken by EPA in the August 9, 2023, final rule.

DATES: Effective September 8, 2023.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2021–0406. 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 if at all possible, 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: Sarah LaRocca, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Ms. LaRocca can be reached via electronic mail at *larocca.sarah@epa.gov* or via telephone at (404) 562–8994.

SUPPLEMENTARY INFORMATION: EPA published a final rule in the **Federal Register** on August 9, 2023 (88 FR 53795), titled ''Air Plan Approval; North Carolina; Bulk Gasoline Plants, Terminals Vapor Recovery Systems.'' The final rule approved changes to the following regulations in North Carolina's SIP: 15A North Carolina Administrative Code, Subchapter 02D, Rules .0926, *Bulk Gasoline Plants;*[1] .0927, *Bulk Gasoline Terminals;*[2] .0932, *Gasoline Cargo Tanks and Vapor Collection Systems;* and .2615, *Determination of Leak Tightness and Vapor Leaks.* However, the **Federal Register** document contained an error in the instructions regarding amendments to the table titled ''EPA-Approved North Carolina Regulations'' found at 40 CFR 52.1770(c)(1). *See* 88 FR 53797. In the instructions, EPA inadvertently referred to the table entries to be amended as ''Section .0926,'' ''Section .0927,'' ''Section .0932,'' and ''Section .2615'' instead of ''Rule .0926,'' ''Rule .0927,'' ''Rule .0932,'' and ''Rule .2615'' and therefore inadvertently sought to replace, rather than revise, those entries. EPA is now correcting that error.

Correction

§ 52.1770 [Corrected]

■ In FR Doc. 2023–16564, published at 88 FR 53795 in the issue of August 9, 2023, on page 53797, in the third column, amendatory instruction 2 for § 52.1770 is corrected to reads as follows:

2. In § 52.1770, amend the table in paragraph (c)(1) by revising the entries ''Rule .0926,'' ''Rule .0927,'' ''Rule .0932,'' and ''Rule .2615'' to read as follows:

Dated: August 25, 2023.

Carol Kemker,

Acting Regional Administrator, Region 4.

[FR Doc. 2023–18709 Filed 8–30–23; 8:45 am]

BILLING CODE 6560–50–P

[1] In Paragraph (n) of Rule .0926, North Carolina's Rule references Rule 02D .0960 which is not in the SIP. The Division of Air Quality (DAQ) withdrew that reference in Paragraph (n) from the April 13, 2021, SIP revision.

[2] Similar to the changes in Rule 02D .0926(n), Rule 02D .0927(k) also references Rule 02D .0960 which is not in the SIP. DAQ withdrew that reference in Paragraph (k) from the April 13, 2021, SIP revision.

Proposed Rules

Federal Register
Vol. 88, No. 168
Thursday, August 31, 2023

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 ENERGY

10 CFR Part 430

[EERE–2019–BT–STD–0036]

RIN 1904–AE82

Energy Conservation Program: Energy Conservation Standards for Consumer Boilers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notification of public meeting and webinar.

SUMMARY: The Energy Policy and Conservation Act, as amended (EPCA), prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including consumer boilers. DOE previously proposed amended energy conservation standards for consumer boilers in a notice of proposed rulemaking (NOPR) published in the **Federal Register** on August 14, 2023, which also announced a public meeting via webinar to receive input on these proposed standards and associated analyses and results. On August 15, 2023, DOE received a letter from the Air-Conditioning, Heating & Refrigeration Institute (AHRI) asking the Department to extend the NOPR comment period by 30 days and also to hold an in-person public meeting regarding the NOPR. In this document, DOE grants AHRI's request for an in-person meeting and announces that the public meeting will now be held in person, in addition to being broadcast as a webinar. DOE is denying AHRI's request for a comment period extension for the reasons explained in this document.

DATES: *Meeting:* DOE will hold a public meeting on Tuesday, September 12, 2023 from 10 a.m. to 3 p.m., in Arlington, VA. This meeting will also be broadcast as a webinar.

ADDRESSES: The public meeting will be held at 1000 Wilson Boulevard, Suite 1400, Arlington, VA 22209. See the **SUPPLEMENTARY INFORMATION** (Public Participation) section for further details, including procedures for attending the in-person meeting, webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (240) 597–6737. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–5827. Email: *Eric.Stas@hq.doe.gov.*

For further information on how to participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: On August 14, 2023, DOE published a NOPR in the **Federal Register** titled ''Energy Conservation Standards for Consumer Boilers,'' which seeks to determine whether more-stringent standards would be technologically feasible and economically justified and would result in significant energy savings. 88 FR 55128. That document, which proposes amended energy conservation standards for consumer boilers, provides a 60-day public comment period ending on October 13, 2023. The NOPR also scheduled a public meeting webinar to discuss the consumer boilers NOPR and to receive input on these proposed standards and associated analyses and results from 1 p.m. to 4 p.m. on Tuesday, September 12, 2023.

On August 15, 2023, DOE received a letter [1] from AHRI asking the Department to extend the Consumer Boilers energy conservation standards NOPR comment period by 30 days and also to hold an in-person public meeting regarding the NOPR. AHRI stated that their members need additional time to consider and collect data on this topic.

After carefully considering AHRI's requests, the Department has decided to grant the request for an in-person public meeting at the date and time previously scheduled in the August 14, 2023 Consumer Boilers NOPR. Consequently, DOE will be hosting an in-person public meeting in addition to the webinar. Please note that attendance will be limited for the in-person public meeting do to room size capacity limits.

DOE has decided to deny AHRI's request for a comment period extension. The Department continues to believe that the comment period length is appropriate and provides a meaningful opportunity for interested parties to comment on the NOPR. It is noted that DOE also posted a pre-publication copy of the NOPR on the DOE website and notified stakeholder organizations of its availability via email on July 28, 2023, which provided many stakeholders with another 17 days of review in addition to the 60-day comment period.

Public Participation

Participation in the Public Meeting and Webinar

The time, date and location of the public meeting are listed in the **DATES** and **ADDRESSES** sections of this document. If you plan to attend the public meeting, you must notify the Appliance and Equipment Standards Program staff no later than September 8, 2023, either by phone at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.* Please note advance registration is required and capacity in the meeting room will be limited.

Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed.

DOE requires visitors to have laptops and other devices, such as tablets, checked upon entry into the building. Any person wishing to bring these devices into the Forrestal Building will

[1] *See* Docket No. EERE–2019–BT–STD–0036, which is available at *www.regulations.gov.*

be required to obtain a property pass. Visitors should avoid bringing these devices, or allow an extra 45 minutes to check in. Please report to the visitor's desk to have devices checked before proceeding through security.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS), there have been recent changes regarding ID requirements for individuals wishing to enter Federal buildings from specific States and U.S. territories. DHS maintains an updated website identifying the State and territory driver's licenses that currently are acceptable for entry into DOE facilities at *www.dhs.gov/real-id-enforcement-brief.* A driver's license from a State or territory identified as not compliant by DHS will not be accepted for building entry and one of the alternate forms of ID listed below will be required. Acceptable alternate forms of Photo-ID include U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by States and territories as identified on the DHS website (Enhanced licenses issued by these States and territories are clearly marked Enhanced or Enhanced Driver's License); a military ID or other Federal government-issued Photo-ID card.

In addition, you can attend the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *www.energy.gov/eere/buildings/public-meetings-and-comment-deadlines.* Participants are responsible for ensuring their systems are compatible with the webinar software.

Procedure for Submitting Prepared General Statements for Distribution

Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address shown in the **ADDRESSES** section at the beginning of this document. The request and advance copy of statements must be received at least one week before the public meeting and are to be emailed. Please include a telephone number to enable DOE staff to make follow-up contact, if needed.

Conduct of the Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the webinar/public meeting. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the webinar and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the proposed rulemaking.

The webinar will be conducted in an informal, conference style. DOE will present a general overview of the topics addressed in this proposed rulemaking, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this proposed rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will permit, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this proposed rulemaking. The official conducting the webinar will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of the August 14, 2023 NOPR. In addition, any person may buy a copy of the transcript from the transcribing reporter.

Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notification of public meeting and webinar.

Signing Authority

This document of the Department of Energy was signed on August 28, 2023, by Francisco Alejandro Moreno, Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 28, 2023.

Treena V. Garrett,

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

[FR Doc. 2023–18850 Filed 8–30–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 21

[Docket No.: FAA–2022–1378]

Proposed Primary Category Design Criteria; ICON Aircraft, Inc., Model A5–B Airplane

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of availability; request for comments.

SUMMARY: This document announces the existence of and requests comments on the proposed airworthiness design criteria for acceptance for the type certification of the ICON Aircraft, Inc., Model A5–B airplane under the regulations for primary category aircraft.

DATES: The FAA must receive comments by October 2, 2023.

ADDRESSES: Send comments identified by Docket No. FAA–2022–1378 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

• *Hand Delivery of Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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

Privacy: The FAA will post all comments it receives, without change, to *https://www.regulations.gov,* including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *https://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *https://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Raymond N. Johnston, Avionics Navigation & Flight Deck Unit (AIR–626B), Avionics & Electrical Systems Section, Technical Policy Branch, Policy & Standards Division, Aircraft Certification Service, Federal Aviation Administration, 901 Locust Street, Room 301, Kansas City, MO 64106; phone (816) 329–4159, fax (816) 329–4090, email *raymond.johnston@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. Please identify Docket No. FAA–2022–1378 on all submitted correspondence. The most helpful comments reference a specific portion of the airworthiness design criteria, explain the reason for any recommended change, and include supporting data.

Except for Confidential Business Information as described in the following paragraph, and other information as described in title 14, Code of Federal Regulations (14 CFR) 11.35, the FAA will file in the docket all comments received, as well as a report summarizing each substantive public contact with FAA personnel concerning these proposed airworthiness design criteria. Before acting on this proposal, the FAA will consider all comments received on or before the closing date for comments. The FAA will consider comments filed late if it is possible to do so without incurring delay. The FAA may change these airworthiness design criteria based on received comments.

Confidential Business Information

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 document 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 document, 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 document. Submissions containing CBI should be sent to the individual listed under **FOR FURTHER INFORMATION CONTACT**. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this document.

Background

The primary category for aircraft was created specifically for simple, low performance personal aircraft. 14 CFR 21.17(f) provides a means for applicants to propose airworthiness criteria for their particular primary category aircraft. The FAA procedure establishing appropriate airworthiness criteria includes reviewing and possibly revising the applicant's proposal, publication of the submittal in the **Federal Register** for public review and comment and addressing the comments. After all necessary revisions, the criteria are published as approved FAA airworthiness criteria. When the FAA finds that a primary category aircraft design meets these airworthiness criteria, and no features or characteristics exist that make the aircraft unsafe for its intended use, the applicant is entitled to a type certificate (TC) for the design in accordance with § 21.24. Airplanes that are manufactured under a production certificate and conform to the approved type design may then be eligible for a special airworthiness certification issued in accordance with § 21.184(a).

Both domestic and imported light-sport aircraft (LSA) that comply with an FAA-accepted consensus standard and meet the other eligibility requirements in § 21.190 may operate in US airspace with a special airworthiness certificate. The FAA periodically issues a notice of availability (NOA) for new and revised LSA airworthiness criteria, including ASTM International, formerly known as American Society for Testing and Materials, Committee F37, consensus standards.[1] Primary category airplanes also operate with a special airworthiness certificate and are subject to similar operational limitations and privileges. ICON Aircraft, Inc., applied for a TC for the Model A–5B on August 3, 2020. Under § 21.17(c), an application for type certification is effective for three years, unless the FAA approves a longer period. Section 21.17(d) provides that, where a TC has not been issued within the time limit established under § 21.17(c), the applicant may file for an extension and update the designated applicable regulations in the type certification basis. Because the project was not certificated within three years after the application date above, the FAA approved the applicant's request to extend the application for type certification. As a result, the date of the updated type certification basis is August 7, 2023. ICON Aircraft, Inc., proposed to maintain a common type design between the LSA and primary category aircraft. Accordingly, these proposed airworthiness design criteria would apply the same ASTM LSA consensus standards as the applicable airworthiness criteria for a primary category TC for the ICON Aircraft, Inc., Model A–5B airplane because that airplane design meets the other requirements and limitations for LSA. The FAA allows use of criteria in GAMA Specification No. 1 for an LSA pilot's operating handbook as an alternative to the ASTM standard for a pilot's operating handbook, as detailed in Tables 1 and 5 below. In certifying the ICON Aircraft, Inc., Model A–5B as a primary category airplane design utilizing the ASTM LSA consensus standards, the design would meet the limitations for both LSA and primary

[1] FAA Accepted LSA Standards, FAA NOA Information, *https://www.faa.gov/aircraft/gen_av/light_sport.* The LSA NOA information maintained on the FAA website includes historical information about the NOA issued February 23, 2022, for ASTM consensus standards that the FAA accepted for certification under the provisions of the Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft rule.

category airplanes as stated in 14 CFR 1.1 and § 21.24, respectively.

The ICON Model A5–B airplane will utilize a Rotax 912 iS Sport piston engine certified by European Union Aviation Safety Agency (EASA TC E.121) with additional FAA validation requirements to account for differences between EASA CS–E requirements and FAA 14 CFR part 33 requirements. The ICON A5–B airplane will utilize a Sensenich 3-blade composite propeller that conforms with the ASTM consensus standard for propellers identified in Tables 1 and 3 of these proposed airworthiness design criteria. The FAA does not plan to issue TCs for the engine or the propeller.

For continued operational safety (COS) requirements, the applicant would need to utilize the processes outlined in ASTM F3198–18 identified in Tables 1 and 7 of these proposed airworthiness design criteria to develop a COS program. Some differences exist between FAA processes for COS for primary category aircraft and those outlined for LSA in ASTM F3198–18. The operational safety risk assessment information in the appendix of ASTM F3198–18 would need to be utilized by the TC holder, except notification to the FAA is required for reportable events identified in § 21.3. The FAA will then utilize a risk assessment process in determining if mandatory action is required.

Authority Citation

The authority citation for these proposed airworthiness design criteria is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, and 44704.

Proposed Airworthiness Criteria for Acceptance Under the Primary Category

This document prescribes airworthiness criteria for the issuance of a TC for the ICON Aircraft, Inc., Model A5–B airplane, a primary category airplane, and its powerplant installation. The FAA proposes the airplane certification basis as listed in Tables 1 through 8 below.

TABLE 1—AIRPLANE CERTIFICATION BASIS

[The following certification basis, established under the provisions of § 21.17(f), is appropriate for the ICON Model A5–B airplane:]

Subject	Consensus standard or regulation	Title and description
Primary Type Certification	Sections 21.17(f) and 21.24, both at amendment 21–100.	''Designation of applicable regulations'', and ''Issuance of type certificate: primary category aircraft.''
Aircraft Design and Performance.	ASTM F2245–20	''Standard Specification for Design and ''Performance of a Light Sport Airplane'' as modified by Table 2 of these airworthiness design criteria.
Engine	14 CFR part 33, Amendment 33–34.	The FAA will accept an engine certified by EASA to CS–E at amendment 6 that meets the additional criteria in Table 8 of these airworthiness design criteria.
Propeller	ASTM F2506–13	''Standard Specification for Design and Testing of Light Sport Aircraft Propellers'' as modified by Table 3 of these airworthiness design criteria.
Noise	14 CFR part 36, Amendment 36–31.	''Noise Standards: Aircraft Type and Airworthiness Certification''.
Airframe Emergency Parachute	ASTM F2316–12	''Standard Specification for Airframe Emergency Parachutes'' as modified by Table 4 of these airworthiness design criteria.
Airplane Flight Manual or Pilot's Operating Handbook.	ASTM F2746–14; Or GAMA Specification No. 1, rev October 18, 1996.	''Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Aircraft'' as modified by Table 5 of these airworthiness design criteria.
Maintenance Manual	ASTM F2483–18	''Standard Practice for Maintenance and the Development of Maintenance Manuals for Light Sport Aircraft'' as modified by Table 6 of these airworthiness design criteria.
Continued Operational Safety (COS).	ASTM F3198–18	''Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program'' as modified by Table 7 of these airworthiness design criteria.

TABLE 2—MODIFICATIONS APPLICABLE TO ASTM F2245–20 ''STANDARD SPECIFICATIONS FOR DESIGN AND PERFORMANCE OF LIGHT SPORT AIRCRAFT''

Requirements:
Include all sections of ASTM F2245–20 except section 9.1.4. Change section 1.1 to: ''This specification covers basic airworthiness requirements for the design of a fixed-wing airplane.'' Change section 1.2 to: ''This specification is applicable to the design of a primary category airplane limited to two seats.''

TABLE 3—MODIFICATIONS APPLICABLE TO ASTM F2506–13 ''STANDARD SPECIFICATION FOR DESIGN AND TESTING OF LIGHT SPORT AIRCRAFT PROPELLERS''

Requirements:
Include all sections of ASTM F2506–13 except section 10.

TABLE 4—MODIFICATIONS APPLICABLE TO ASTM F2316–12 ''STANDARD SPECIFICATION FOR AIRFRAME EMERGENCY PARACHUTES''

Requirements:
Include all sections of ASTM F2316–12 except section 12.

TABLE 5—MODIFICATIONS APPLICABLE TO ASTM F2746–14 ''STANDARD SPECIFICATION FOR PILOT'S OPERATING HANDBOOK (POH) FOR LIGHT SPORT AIRCRAFT''

Requirements:
The airplane flight manual (AFM) must comply with all sections of ASTM F2746–14, as modified by this table, except sections 1.3, 4.6, and 7, or alternatively, the airplane flight manual must comply with GAMA Specification No. 1 [2] issued February 15, 1975, and revised October 18, 1996, in which case the following modifications do not apply. In addition to ASTM F2746–14, each part of the AFM indicated below must be approved, segregated, identified, and clearly distinguished from unapproved parts: • Chapter 2 Limitations; • Chapter 3 Emergency Procedures; • Chapter 5 Performance; • Chapter 6: ○ Weight and Balance Chart (see section 6.10.1 of ASTM F2746–14); ○ Operating Weights and Loading (see section 6.10.2 of ASTM F2746–14); ○ Center of Gravity (CG) Range and Determination (see section 6.10.3 of ASTM F2746–14); • Chapter 8: ○ Approved Fuel Grades and Specifications (see section 6.12.5.1 of ASTM F2746–14); ○ Approved Oil Grades and Specifications (see section 6.12.5.2 of ASTM F2746–14). In addition to ASTM F2746–14, non-approved information in the AFM must be presented in a manner acceptable to the FAA. Change section 6.4.1 of ASTM 2746–14 to: ''A list of the standards used for the design, construction, continued airworthiness, and reference compliance with this standard.''

TABLE 6—MODIFICATIONS APPLICABLE TO ASTM F2483–18 ''STANDARD PRACTICE FOR MAINTENANCE AND THE DEVELOPMENT OF MAINTENANCE MANUALS FOR LIGHT SPORT AIRCRAFT''

Requirements:
Include all sections of ASTM F2483–18 *except:* • Section 3.1.7 • Section 3.1.7.1 • Section 3.1.8 • Section 4 • Note 1 in section 5 • Section 5.3.2 • Section 5.3.3 • Section 5.3.6 • Section 6.1 • Note 5 in section 6.1 • Section 8 and all subsections and notes • Section 9 and all subsections • Section 10 and all subsections • Section 11 and all subsections and notes • Section 12 and all subsections • Annex A1 In addition to ASTM F2483–18, a maintenance manual containing the information that the applicant considers essential for proper maintenance must be provided as indicated in § 21.24(a)(2)(iii). In addition to ASTM F2483–18, the part of the manual containing service life limitations, the replacement or overhaul of parts, components, and accessories subject to such limitations must be approved, identified, and clearly distinguished from each other unapproved part of the maintenance manual. Change section 3.1.9 to: ''*maintenance manual(s)*—manual provided by the type design holder that specifies maintenance, repairs, or alterations authorized by the manufacturer.'' Change section 3.1.11 to: ''*manufacturer*—any entity engaged in the production of, or component used on, a type certified primary category airplane. Change section 5.3 to: ''*Level of Certification*—When listing the qualification level needed to perform a task, the type certificate holder must use the appropriate qualifications from the regulations for aircraft maintenance indicated in 14 CFR part 43, appendix A.'' Change Note 4 in section 5.3.1 to: ''Primary category aircraft owners may perform maintenance as outlined in part 43, appendix A.'' Change section 6.2 to: ''Typical tasks considered as line maintenance include:''

[2] GAMA Specification No. 1.

TABLE 7—MODIFICATIONS APPLICABLE TO ASTM F3198–18 "STANDARD SPECIFICATION FOR LIGHT SPORT AIRCRAFT MANUFACTURER'S CONTINUED OPERATIONAL SAFETY (COS) PROGRAM"

Requirement:
Include all sections of ASTM F3198–18 *except:* • Section 1 and all subsections • Section 5.2 and all subsections • Section 5.3 and all subsections • Section 6.1.1.3 • Section 6.1.1.4 • Section 7.7 and all subsections • Section 8.1.2.1 • Section 8.2 and all subsections • Section 10
Change section 4.1 to: "The purpose of this specification is to establish, by the manufacturer, a method by which unsafe conditions and service difficulty issues are reported, evaluated, and corrected. The type certificate holder is responsible to report failures, malfunctions or defects to the FAA as outlined in § 21.3."
Replace "manufacturer" with "type certificate holder" throughout section 7.

TABLE 8—FAA VALIDATION OF EASA STATE OF DESIGN RECIPROCATING AIRCRAFT ENGINES

[In addition to the EASA CS–E, amendment 6 requirements,[3] the following requirements from 14 CFR part 33, amendment 33–34 also apply.]

Subject	14 CFR part 33
Instructions for Continued Airworthiness (ICA)	Section 33.4, appendices A33.1(b), A33.2, A33.3(b) and (c), and A33.4(a)(2).
Engine ratings and operating limitations including reciprocating engine limits.	Sections 33.7(b)(6) and (b)(8).
Durability (Propeller blade pitch control systems)	Section 33.19(b).
Turbine, compressor, fan, and turbosupercharger rotor overspeed	Section 33.27.
Turbocharger rotors	Section 33.34.
Lubrication system	Sections 33.39(a) and (c).
Vibration test	Sections 33.43(a) and (c).
Endurance test	Section 33.49(d).

Issued in Kansas City, Missouri, on 24 August, 2023.

Patrick R. Mullen,

Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.

[FR Doc. 2023–18679 Filed 8–30–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1723; Project Identifier MCAI–2023–00457–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS 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 all Airbus SAS Model A330–200 Freighter series airplanes. This proposed AD was prompted by a widespread fatigue damage (WFD) evaluation on Airbus SAS Model A330–200 Freighter series airplanes, which found that the circumferential joint at Frame 58 (near the rear fuselage) is susceptible to WFD. This proposed AD would require a modification to reinforce the circumferential joints at Frame 58 and, if necessary, corrective action, as specified in a European Union Aviation Safety Agency (EASA) 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 October 16, 2023.

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–2023–1723; 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 material that is proposed for IBR in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at

[3] CS–E, Amendment 6—Aircraft cybersecurity.

ad.easa.europa.eu. It is also available at *regulations.gov* under Docket No. FAA–2023–1723.

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

FOR FURTHER INFORMATION CONTACT: Tim Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3667; email: *timothy.p.dowling@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–2023–1723; Project Identifier MCAI–2023–00457–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 Tim Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3667; email: *timothy.p.dowling@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

Fatigue damage can occur locally, in small areas or structural design details, or globally, in widespread areas. Multiple-site damage is widespread damage that occurs in a large structural element such as a single rivet line of a lap splice joining two large skin panels. Widespread damage can also occur in multiple elements such as adjacent frames or stringers. Multiple-site damage and multiple-element damage cracks are typically too small initially to be reliably detected with normal inspection methods. Without intervention, these cracks will grow, and eventually compromise the structural integrity of the airplane. This condition is known as WFD. It is associated with general degradation of large areas of structure with similar structural details and stress levels. As an airplane ages, WFD will likely occur, and will certainly occur if the airplane is operated long enough without any intervention.

An FAA final rule (''Aging Airplane Program: Widespread Fatigue Damage;'' 75 FR 69746, November 15, 2010) became effective on January 14, 2011, and amended 14 CFR parts 25, 26, 121, and 129 (commonly known as the WFD rule). The WFD rule requires certain actions to prevent structural failure due to WFD throughout the operational life of certain existing transport category airplanes and all of these airplanes that will be certificated in the future. Design approval holders (DAHs) of existing and future airplanes subject to the WFD rule are required to establish a limit of validity (LOV) of the engineering data that support the structural maintenance program. Operators affected by the WFD rule may not fly an airplane beyond its LOV, unless an extended LOV is approved.

The WFD rule does not require identifying and developing maintenance actions if the DAHs can show that such actions are not necessary to prevent WFD before the airplane reaches the LOV. Many LOVs, however, do depend on accomplishment of future maintenance actions. As stated in the WFD rule, any maintenance actions necessary to reach the LOV will be mandated by airworthiness directives through separate rulemaking actions.

In the context of WFD, this action is necessary to enable DAHs to propose LOVs that allow operators the longest operational lives for their airplanes, and still ensure that WFD will not occur. This approach allows for an implementation strategy that provides flexibility to DAHs in determining the timing of service information development (with FAA approval), while providing operators with certainty regarding the LOV applicable to their airplanes.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2023–0053, dated March 14, 2023 (EASA AD 2023–0053) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A330–223F and –243F airplanes. The MCAI states that within the scope of WFD evaluations on Model A330–200 Freighter series airplanes, it was determined that the circumferential joint at Frame 58 (near rear fuselage) is susceptible to WFD. WFD, if not corrected, may lead to crack initiation and undetected propagation, which could affect 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–2023–1723.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0053 specifies procedures for a modification (including rotating probe inspections for discrepancies and measurement of the maximum hole diameter at any point in the fastener hole bores on the circumferential joints) to reinforce the circumferential joints at Frame 58 and, if any discrepancies (cracking) are found, corrective action (contacting the manufacturer for instructions and accomplishing those instructions). 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 accomplishing the actions specified in EASA AD 2023–0053 described previously, except for any differences identified as exceptions in the regulatory text 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 EASA AD 2023–0053 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0053 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 2023–0053 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 2023–0053. Service information required by EASA AD 2023–0053 for compliance will be available at *regulations.gov* under Docket No. FAA–2023–1723 after the FAA final rule is published.

Explanation of Compliance Time

The compliance time for the replacement specified in this proposed AD for addressing WFD was established to ensure that certain structure is replaced before WFD develops in airplanes. Standard inspection techniques cannot be relied on to detect WFD before it becomes a hazard to flight. The FAA will not grant any extensions of the compliance time to complete any AD-mandated service bulletin related to WFD without extensive new data that would substantiate and clearly warrant such an extension.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 6 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
368 work-hours × $85 per hour = $31,280	$7,700	$38,980	$233,880

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions specified in this proposed AD.

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 SAS: Docket No. FAA–2023–1723; Project Identifier MCAI–2023–00457–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by October 16, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A330–223F and –243F airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a widespread fatigue damage (WFD) evaluation on Model A330–200 Freighter series airplanes, which found that the circumferential joint at Frame 58 (near the rear fuselage) is susceptible to WFD. The FAA is issuing this AD to address WFD in the affected area. The unsafe condition, if not corrected, may lead to crack initiation and undetected propagation, which could affect 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, European Union Aviation Safety Agency (EASA) AD 2023–0053, dated March 14, 2023 (EASA AD 2023–0053).

(h) Exceptions to EASA AD 2023–0053

(1) Where EASA AD 2023–0053 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0053.

(3) Where paragraph (2) of EASA AD 2023–0053 specifies ''if, during the accomplishment of any inspection, which is part of the modification as required by paragraph (1) of this AD, any discrepancy, as identified in the SB, is detected, before next flight, contact Airbus for approved instructions and accomplish those instructions accordingly,'' this AD requires replacing those words with ''if, during the accomplishment of any inspection, which is part of the modification as required by paragraph (1) of this AD, any cracking is detected, the cracking must be repaired before further flight using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.''

(i) 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 International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* 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 EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Tim Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3667; email: *timothy.p.dowling@faa.gov.*

(k) 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) European Union Aviation Safety Agency (EASA) AD 2023–0053, dated March 14, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0053, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +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 material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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

Issued on August 24, 2023.

Victor Wicklund,

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

[FR Doc. 2023–18693 Filed 8–30–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1810; Project Identifier MCAI–2023–00267–T]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); 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 Airbus Canada Limited Partnership Model BD–500–1A11 airplanes. This proposed AD was prompted by a manufacturing issue with an electrical connector that may prevent the connector from self-locking. This proposed AD would require removing the affected connector, installing a new connector, and testing the emergency power supply units (EPSUs), 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 October 16, 2023.

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–2023–1810; 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 material that is proposed for IBR in this NPRM, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email: *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website: *tc.canada.ca/en/aviation.* It is also available at *regulations.gov* under Docket No. FAA–2023–1810.

• You may view this service information 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: William Reisenauer, 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–2023–1810; Project Identifier MCAI–2023–00267–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 William Reisenauer, 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–2023–08, dated February 13, 2023 (Transport Canada AD CF–2023–08) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus Canada Limited Partnership (formerly C Series Aircraft Limited Partnership (CSALP), Bombardier Inc.) Model BD–500–1A11 airplanes. The MCAI states a manufacturing molding issue with an electrical connector may prevent the connector from self-locking. The connector may become loose over time, preventing the charging of EPSUs 3 and 4 and lead to the loss of emergency lights, possibly resulting in injury to occupants during an evacuation.

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–2023–1810.

Related Service Information Under 1 CFR Part 51

Transport Canada AD CF–2023–08 specifies procedures for removing the affected connector, installing a new connector, and testing the EPSUs. 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** section.

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 accomplishing the actions specified in Transport Canada AD CF–2023–08 described previously, except for any differences identified as exceptions in the regulatory text 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–2023–08 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with Transport Canada AD CF–2023–08 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–2023–08 for compliance will be available at *regulations.gov* under Docket No. FAA–2023–1810 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 4 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
3.5 work-hours × $85 per hour = $298	$1,534	$1,832	$7,328

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 Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Docket No. FAA–2023–1810; Project Identifier MCAI–2023–00267–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by October 16, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (Type Certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada AD CF–2023–08, dated February 13, 2023 (Transport Canada AD CF–2023–08).

(d) Subject

Air Transport Association (ATA) of America Code: 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a manufacturing molding issue with an electrical connector that may prevent the connector from self-locking. The FAA is issuing this AD to ensure the connector does not become loose over time, and prevent the charging of emergency power supply units (EPSUs) 3 and 4. The unsafe condition, if not addressed, could result in loss of emergency lights, possibly resulting in injury to occupants during an evacuation.

(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–2023–08.

(h) Exception To Transport Canada AD CF–2023–08

Where Transport Canada AD CF–2023–08 refers to its effective date, this AD requires using the effective date of this AD.

(i) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the actions required by this AD can be accomplished, provided no passengers are onboard.

(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 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.* 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 Airbus Canada Limited Partnership'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 William Reisenauer, 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–2023–08, dated February 13, 2023.

(ii) [Reserved]

(3) For Transport Canada AD CF–2023–08, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email: *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website: *tc.canada.ca/en/aviation.*

(4) You may view this service information 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 service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on August 25, 2023.

Victor Wicklund,

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

[FR Doc. 2023–18801 Filed 8–30–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF EDUCATION

34 CFR Chapter VI

[Docket ID ED–2023–OPE–0123]

Negotiated Rulemaking Committee; Negotiator Nominations and Schedule of Committee Meetings

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Intent to establish rulemaking committee.

SUMMARY: We announce our intention to establish a negotiated rulemaking committee to prepare proposed regulations for the Federal Student Aid programs authorized under title IV of the Higher Education Act of 1965, as amended (HEA). The committee will include representatives of organizations or groups with interests that are significantly affected by the subject matter of the proposed regulations. We request nominations for individual negotiators who represent key stakeholder constituencies for the issues to be negotiated to serve on the committee. The Department has also set a schedule for committee meetings.

DATES: We must receive your nominations for negotiators to serve on the committee on or before September 14, 2023. The dates and times of the committee meetings are set out in the *Schedule for Negotiations* section in the **SUPPLEMENTARY INFORMATION** section. All meetings will be virtual.

ADDRESSES: Please email your nominations for negotiators to *negregnominations@ed.gov.* If you are unable to email your nomination, please contact Jean-Didier Gaina. Telephone: (202) 987–1333. Email: *Jean-Didier.Gaina@ed.gov.*

FOR FURTHER INFORMATION CONTACT: 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.* For information about the content of this document, including additional information about the negotiated rulemaking process, please contact Jean-Didier Gaina. Telephone: (202) 987–1333. Email: *Jean-Didier.Gaina@ed.gov,* for information on the nomination submission process, Email: *negregnominations@ed.gov.*

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

SUPPLEMENTARY INFORMATION:

Background

On July 6, 2023, we published in the **Federal Register** (88 FR 43069) an announcement of our intent to establish a negotiated rulemaking 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, release, or compromise of Federal student loans by the Department. We also announced a public hearing at which interested parties could comment on the topics for negotiation suggested by the Department and suggest additional topics for consideration for action by the negotiated rulemaking committee. That hearing took place virtually on July 18, 2023.

You may view written comments submitted in response to the aforementioned **Federal Register** notice through the Federal eRulemaking Portal at *www.regulations.gov.* Instructions for finding comments are available on the site under ''FAQ.'' Enter Docket ID ED–2023–OPE–0123 in the search box to locate the appropriate docket.

Committee Topics

After considering the information received at the public hearing and the written comments, we have decided to establish the Student Loan Relief Committee (Committee) to address the topics of the authorities granted to the Secretary in the HEA, including the provisions related to the modification, waiver, release, or compromise of Federal student loans in section 432(a) of the HEA. Depending on the outcome of the discussions during negotiated rulemaking and the details of the proposed regulations, different sections in 34 CFR parts 30, 682, and 685 may be revised through the final regulations.

We intend to select negotiators for the Committee who represent the interests of those significantly affected by the topics proposed for negotiation. In so doing, we will comply with the requirement in section 492(b)(1) of the HEA that the individuals selected must have demonstrated expertise or experience in the relevant topics proposed for negotiations. We will also select negotiators who reflect the diversity among program participants, in accordance with section 492(b)(1) of the HEA. Our goal is to establish a committee that will allow significantly affected parties to be represented while keeping the size manageable.

We generally select a primary and alternate negotiator for each constituency represented on a committee. The primary negotiator participates for the purpose of determining consensus. The alternate participates for the purpose of determining consensus in the absence of the primary negotiator. The Department will provide more detailed information to both primary and alternate negotiators selected to participate on the Committee about the logistics and protocols of the meetings.

Members of the public may observe the Committee meetings, will have access to individuals representing their constituencies, and may be able to participate in informal working groups on issues between the meetings. Members of the public will have 30 minutes at the end of each day to provide comments.

Constituencies for Negotiator Nominations

We have identified the following constituencies as having interests that are significantly affected by the topics proposed for negotiation. We plan to include negotiators who represent these constituencies. We particularly encourage individuals or organizations representing the interests of historically underserved or low-income communities to nominate themselves. Nominations should include evidence of the nominee's specific knowledge of the modification, waiver, release, or compromise of Federal student loans. The Department strongly encourages nominees to list all constituencies under which they would like to be considered. The Department reserves the discretion to place a nominee in a constituency based upon their background and experience even if the individual was not nominated for that specific category. Constituencies for the Committee are:

(1) Student loan borrowers who attended programs of two years or less.

(2) Student loan borrowers who attended four-year programs.

(3) Student loan borrowers who attended graduate programs.

(4) Currently enrolled postsecondary education students.

(5) U.S. military service members, veterans, or groups representing them.

(6) Civil rights organizations.

(7) Legal assistance organizations that represent students or borrowers.

(8) State officials, including State higher education executive officers, State authorizing agencies, and State regulators of institutions of higher education.

(9) State attorneys general.

(10) Public institutions of higher education, including two-year and four-year institutions.

(11) Private nonprofit institutions of higher education.

(12) Proprietary institutions.

(13) Historically Black Colleges and Universities, Tribal Colleges and Universities, and Minority-serving institutions (institutions of higher education eligible to receive Federal assistance under title III, parts A and F, and title V of the HEA).

(14) Federal Family Education Loan (FFEL) lenders, servicers, or guaranty agencies.

The Department is particularly interested in ensuring the primary and alternate negotiators who represent the different borrower and student constituencies reflect a variety of experiences with student loans and postsecondary education, including attending different types of institutions, for different types of programs borrowing a Parent PLUS loan to pay for a dependent student's education, borrowing either Direct or FFEL loans, and receiving a Pell grant. We also seek negotiators who have borrowed varied amounts and have varied repayment histories. We encourage nominations that provide the Department with diverse information about borrowing and repayment experiences.

The goal of the committee is to develop proposed regulations that reflect a final consensus of the committee. Consensus means that there is no dissent by any member of a negotiating committee, including the committee member representing the Department.

A negotiator is expected to represent the interests of their constituency and to participate in the negotiations in a manner consistent with the goal of developing proposed regulations on which the committee will reach consensus. If consensus is reached, all members of the organization or group represented by a negotiator are bound by the consensus and are prohibited from commenting negatively on the resulting proposed regulations. The Department will not consider any such negative comments on the proposed regulations that are submitted by a member of such an organization.

Nominations

We request that nominations include the information described in this section.

(1) The name of the nominee;

(2) The name of the constituency (or constituencies) for which the nominee is being nominated (see *Constituencies for Negotiator Nominations*);

(3) The nominee's place of employment or institution at which they are or were enrolled and, if different, the organization the nominee represents;

(4) A resume or evidence of the nominee's expertise and experience in the topics proposed for negotiations; and

(5) The nominee's contact information, including email address, telephone number, and mailing address.

Please see the **ADDRESSES** section for submission information. We will confirm receipt of nominations to the submitter. The Department will provide additional information to those we select to serve as negotiators. Once complete, a list of negotiators will be posted here: *https://www2.ed.gov/policy/highered/reg/hearulemaking/2023/index.html.*

l. The Department will also provide information at that site about how any committee vacancies can be filled at the beginning of the first committee meeting.

Schedule for Negotiations

The Committee will meet for three sessions on the following dates:

Session 1: October 10–11, 2023.

Session 2: November 6–7, 2023.

Session 3: December 11–12, 2023.

Session times will be from 10 a.m. to 12 p.m. and 1 to 4 p.m., with a public comment period from approximately 3:30 to 4 p.m., Eastern time.

All sessions will be conducted virtually and available for the public to view. Individuals who wish to observe the committee meetings will be required to register for each session they would like to observe. We will post registration links 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.

At the end of each day (except for the final day of the final session), the Department will reserve 30 minutes for public comment. 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. 2023–18853 Filed 8–30–23; 8:45 am]

BILLING CODE 4000–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

49 CFR Part 831

[Docket No.: NTSB–2023–0007]

RIN 3147–AA28

Authority of NTSB in Railroad, Pipeline, and Hazardous Materials Investigations

AGENCY: National Transportation Safety Board (NTSB).

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: The National Transportation Safety Board (NTSB) is publishing this advance notice of proposed rulemaking (ANPRM) to seek public feedback on whether it should define the term ''substantial property damage'' as it relates to the agency's authority to investigate railroad accidents. Neither the agency's statute nor the regulation currently defines this term, thus, the NTSB seeks comments on whether defining ''substantial property damage'' would better clarify the scope of regulatory coverage for its railroad investigations. The issues raised in the comments submitted in response to this ANPRM will inform whether and how the NTSB will define this term in its regulation.

DATES: Send comments on or before October 30, 2023.

ADDRESSES: You may send comments, identified by Docket Number (No.) NTSB–2023–0007, by any of the following methods:

- *Federal e-Rulemaking Portal: https://www.regulations.gov.*
- *Email: rulemaking@ntsb.gov.*

- *Fax:* 202–314–6090.
- *Mail/Hand Delivery/Courier:* NTSB, Office of General Counsel, 490 L'Enfant Plaza East SW, Washington, DC 20594.

Instructions: All submissions in response to this ANPRM must include Docket No. NTSB–2023–0007. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket, go to *https://www.regulations.gov* and search Docket No. NTSB–2023–0007.

FOR FURTHER INFORMATION CONTACT: William Thomas (Tom) McMurry, Jr., General Counsel, (202) 314–6080, *rulemaking@ntsb.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Independent Safety Board Act of 1974, as amended, the NTSB is required to ''investigate or have investigated (in detail the Board prescribes) and establish the facts, circumstances, and cause or probable cause of . . . a railroad accident in which there is a fatality or substantial property damage, or that involves a passenger train.'' 49 U.S.C. 1131(a)(1)(C). The NTSB's regulations found at 49 CFR 831.40(a)(1) further explain that the NTSB has the authority to investigate ''railroad accidents, collisions, crashes, derailments, explosions, incidents, and releases in which involve a fatality, substantial property damage, or a passenger train.'' Section 840.2 defines railroad as ''any system of surface transportation of persons or property over rails. It includes, but is not limited to, line-haul freight and passenger-carrying railroads, and rapid transit, commuter, scenic, subway, and elevated railways.''

Notably, the agency's regulation has neither a definition nor a monetary threshold for the term ''substantial property damage'' as reflected in § 831.40(a)(1). The NTSB believes that defining this term will clarify the types of railroad accidents the NTSB will investigate. Thus, the NTSB is soliciting comments on the promulgation of a regulatory definition of ''substantial property damage'' particular to railroad accidents.

To define ''substantial property damage,'' the NTSB has considered regulatory thresholds utilized by the Federal Railroad Administration (FRA) and the Federal Transit Administration (FTA) at the United States Department of Transportation (DOT). The FRA ''[e]nables the safe, reliable, and efficient movement of people and goods along the Nation's railroads.'' [1] The FRA has a monetary threshold for reporting rail equipment accidents/incidents of $11,300 for calendar year (CY) 2022.[2] The NTSB is disinclined to align itself with FRA's threshold as the NTSB believes that $11,300 is too low of a value. However, if the NTSB does promulgate a rule establishing a monetary value for ''substantial property damage,'' the NTSB may consider periodically adjusting for inflation the monetary threshold as the FRA recently did for CY 2022. *See* 85 FR 79130 (Dec. 9, 2020).

By contrast, the FTA, which ''[p]rovides financial and technical assistance to local public transit systems, including buses, subways, light rail, commuter rail, trolleys and ferries,'' [3] does not have a monetary value for reporting major events, but bases reporting requirements on whether there is ''substantial damage'' as defined by FTA.[4] The FTA defines ''substantial damage'' as ''[d]amage to transit or non-transit property including vehicles, facilities, equipment, rolling stock, or infrastructure that disrupts the operations of the rail transit agency and adversely affects the structural strength, performance, or operating characteristics of the of the property, requiring towing, rescue, on-site maintenance, or immediate removal prior to safe operation.'' [5] Notably, excluded from this definition is damage that is limited to: cracked windows; dents, bends, or small puncture holes in the body; broken lights or mirrors; or removal from service under the vehicle's own power for minor repair or maintenance, testing, or video and event recorder download.

The NTSB does have a reporting threshold notification requirement contained in 49 CFR 840.3(b), which requires reporting of accidents with $150,000 damage or more to railroad and nonrailroad property; or $25,000 or more for a passenger train, and railroad and nonrailroad property. The NTSB is considering these monetary values to establish the threshold for ''substantial property damage.'' However, with the different threshold reporting requirements for freight and passenger trains, the NTSB is considering whether the same distinctions should apply to ''substantial property damage.''

Further, the NTSB is considering whether its proposed definition of ''substantial property damage'' should contain a distinction between public railroads and private railroads reporting thresholds. The Board acknowledges, however, that if the NTSB were to define ''substantial property damage'' differently between public and private railroads, doing so may give rise to a question regarding which definition of ''substantial property damage'' applies if there were an accident involving both a public and private railroad.

Accordingly, the public is asked to address any or all of the following questions:

1. Should the NTSB define ''substantial property damage''?
2. If not, why not?
3. If so, how should the NTSB define ''substantial property damage''?
4. If ''substantial property damage'' is defined using a specific dollar amount, what would be a reasonable monetary threshold?
5. How should the NTSB calculate the threshold value of ''substantial property damage''?
6. Should the dollar amount established be indexed for inflation?
7. Should the property damage value be consistent with the reporting threshold established by the FRA? Why or why not?
8. Should the property damage value be consistent with the reporting threshold established by the NTSB? Why or why not?
9. Should ''substantial property damage'' be based on total property damage, railroad property damage, or non-railroad property damage?
10. Should ''substantial property damage'' consider factors other than monetary value?
11. Should there be a distinction in threshold reporting requirements between public railroads and private railroads?
12. And which definition should apply to an accident involving both a public railroad and private railroad?
13. The NTSB has different threshold reporting requirements for freight and passenger trains. Should the definition of ''substantial property damage'' contain a similar distinction?

List of Subjects in 49 CFR Part 831

Aircraft accidents, Aircraft incidents, Aviation safety, Hazardous materials transportation, Highway safety, Investigations, Marine safety, Pipeline safety, Railroad safety.

William T. McMurry, Jr.,

General Counsel.

[FR Doc. 2023–18840 Filed 8–30–23; 8:45 am]

BILLING CODE 7533–01–P

[1] *https://www.transportation.gov/railroads.*

[2] The FRA's Monetary Threshold Notice is available at: *https://railroads.dot.gov/safety-data/forms-guides-publications/guides/monetary-threshold-notice.*

[3] *https://www.transportation.gov/public-transit.*

[4] *https://www.transit.dot.gov/ntd/national-transit-database-ntd-glossary#S.*

[5] *https://www.transit.dot.gov/ntd/national-transit-database-ntd-glossary#S.*

NATIONAL TRANSPORTATION SAFETY BOARD

49 CFR Part 831

[Docket No.: NTSB–2023–0008]

RIN 3147–AA29

Authority of NTSB in Railroad, Pipeline, and Hazardous Materials Investigations

AGENCY: National Transportation Safety Board (NTSB).

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: The National Transportation Safety Board (NTSB) is publishing this advance notice of proposed rulemaking (ANPRM) to seek public feedback on whether it should define the terms ''significant injury to the environment'' and ''substantial property damage'' as they relate to the agency's investigative authority involving pipeline accidents. Neither the agency's statute nor the regulation currently defines these terms; thus, the NTSB seeks comments on whether defining them would better clarify the scope of regulatory coverage for its pipeline investigations. The issues raised in the comments submitted in response to this ANPRM will inform whether and how the NTSB will define these terms in its regulation.

DATES: Send comments on or before October 30, 2023.

ADDRESSES: You may send comments, identified by Docket Number (No.) NTSB–2023–0008, by any of the following methods:

- *Federal e-Rulemaking Portal: https://www.regulations.gov.*
- *Email: rulemaking@ntsb.gov.*
- *Fax:* 202–314–6090.
- *Mail/Hand Delivery/Courier:* NTSB, Office of General Counsel, 490 L'Enfant Plaza East SW, Washington, DC 20594.

Instructions: All submissions in response to this ANPRM must include Docket No. NTSB–2023–0008. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket, go to *https://www.regulations.gov* and search Docket No. NTSB–2023–0008.

FOR FURTHER INFORMATION CONTACT: William Thomas (Tom) McMurry, Jr., General Counsel, (202) 314–6080, *rulemaking@ntsb.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Independent Safety Board Act of 1974, as amended, the NTSB is required to ''investigate or have investigated (in detail the Board prescribes) and establish the facts, circumstances, and cause or probable cause of a pipeline accident in which there is a fatality, substantial property damage, or significant injury to the environment.'' 49 U.S.C. 1131(a)(1)(D). The NTSB's regulations found at 49 CFR 831.40(a)(2) further explain that the NTSB has the authority to investigate ''pipeline accidents, explosions, incidents, and ruptures in which there is a fatality, significant injury to the environment, or substantial property damage.''

Notably, the agency's regulation has neither a definition nor threshold for the terms ''significant injury to the environment'' or ''substantial property damage'' as used in § 831.40(a)(2). The NTSB believes that defining these terms will clarify the types of pipeline accidents that the NTSB will investigate. Thus, the NTSB is soliciting comments on the promulgation of the regulatory definitions of ''significant injury to the environment'' and ''substantial property damage'' particular to pipeline accidents.

The NTSB recognizes that pipeline regulations are more complicated and extensive than what can be realistically covered in this ANPRM as there are various Federal regulations addressing hazardous liquid and natural gas pipelines. Federal agencies with such regulations include the United States Coast Guard (USCG), the Department of Interior (DOI), and the Pipeline and Hazardous Materials Safety Administration (PHMSA) (an operating administration within the U.S. Department of Transportation (DOT)).

For example, there are also hazardous liquid dock lines that are regulated by USCG under 33 CFR part 154 (Facilities Transferring Oil or Hazardous Material in Bulk). Moreover, offshore hazardous liquid and natural gas lines are regulated by DOI under 30 CFR part 250 (Oil and Gas and Sulphur Operations in the Outer Continental Shelf). Additionally, 49 CFR parts 191 (Transportation of Natural and Other Gas by Pipeline: Annual Incident, and Other Reporting), 192 (Transportation of Natural and Other Gas by Pipeline: Minimum Federal Safety Standards), 193 (Liquefied Natural Gas Facilities: Federal Safety Standards), 194 (Response Plans for Onshore Oil Pipelines), and 195 (Transportation of Hazardous Liquids by Pipeline) are PHMSA regulations pertaining to pipeline safety.

In addition to the aforementioned Federal regulations, there are individual state laws regarding intrastate pipelines that the NTSB also has the authority to investigate.

For purposes of this rulemaking, the NTSB finds it appropriate to align its rule with those promulgated by PHMSA, which is ''responsible for regulating and ensuring the safe and secure movement of hazardous materials to industry and consumers by all modes of transportation, including pipelines.'' [1] Accordingly, the NTSB reviewed PHMSA's regulation to better understand how that agency defines both substantial property damage and significant harm to the environment.

While there are various PHMSA regulations as noted above, there are two of particular interest to the NTSB. As will be discussed further below, for substantial property damage, the NTSB is considering adopting the reporting accident requirements provided in 49 CFR 191.9 (Distribution system: Incident report) for natural gas and 49 CFR 195.50 (Reporting Accidents) for hazardous liquids. For significant injury to the environment, the NTSB is considering adopting the standard contained in 49 CFR 194.103 (Significant and Substantial Harm: Operator's Statement).

I. Substantial Property Damage

The NTSB is considering adopting the standards set forth in 49 CFR 191.9 (Distribution system: Incident report), and 49 CFR 191.15 (Transmission systems; gathering systems; liquefied natural gas facilities; and underground natural gas storage facilities: Incident report). The NTSB is also considering reporting pipeline accidents found in 40 CFR 195.50 (Reporting accidents [involving hazardous liquid pipelines]. These regulations require an incident/accident report for each failure in a pipeline system when there is a release of natural gas, hazardous liquid, or carbon dioxide. Section 195.50(d) specifies that an accident report is required ''for each failure in a pipeline system . . . in which there is a release of the hazardous liquid . . .'' resulting in ''[e]stimated property damage, including cost of clean-up and recovery, value of lost product, and damage to the property of the operator or others, or both, exceeding'' a specified amount.

If the NTSB uses PHMSA's monetary threshold above or any other monetary threshold, the NTSB is further considering whether to have its reporting threshold indexed to inflation, which PHMSA does not calculate for hazardous liquids in 49 CFR 195.50(e). By contrast, for natural gas, PHMSA uses a property damage reporting threshold formula that is indexed to inflation in accordance with a formula

[1] *https://www.phmsa.dot.gov/regulations.*

detailed appendix A to part 191 (Procedure for Determining Reporting Threshold).

II. Significant Harm to the Environment

As noted above, the NTSB is considering the standard contained in § 194.103 (Significant and Substantial Harm: Operator's Statement) to define ''significant injury to the environment.'' Section 194.103(a) explains when a line section ''can be expected to cause 'significant and substantial harm to the environment' in the event of a discharge of oil into or on the navigable waters or adjoining shorelines.''

Specifically, that regulation further provides that a line section may result in significant and substantial harm to the environment involving an oil discharge if the pipeline is greater than 6⅝ inches in outside nominal diameter, greater than 10 miles in length, and the line section meets any of the following: has experienced within the previous five years either a release greater than 1,000 barrels, or two or more reportable releases; containing an electric resistance welded pipe, which operates at a maximum pressure that corresponds to a stress level greater than 50 percent of the specified minimum yield strength of the pipe; is located within a 5-mile radius of potentially affected public drinking water intakes and can reasonably be expected to reach such intakes; or located within a 1-mile radius of potentially-affected environmentally sensitive areas, and could reasonably be expected to reach such areas. *See* 49 CFR 194.103(c).

Using PHMSA's regulation as a model, the NTSB proposes the following definition for ''significant injury to the environment'': ''a discharge of 1,000 barrels or more of crude oil, refined petroleum product or anhydrous ammonia; into or on the navigable waters or adjoining shorelines or unusually sensitive areas.'' The NTSB notes that unusually sensitive areas are defined in PHMSA's 49 CFR 195.6 and includes environmentally sensitive areas and drinking water sources.

III. Public Comment

To assist the NTSB in defining ''substantial property damage'' and ''significant injury to the environment'' as those terms relate to pipeline accidents, the public is asked to address any or all of the following questions:

1. Should the NTSB define ''substantial property damage''?
2. How should the NTSB define ''substantial property damage''?
3. As noted above, PHMSA has accident report thresholds for property damage that are indexed to inflation. Should the NTSB's property damage value be consistent with PHMSA's reporting threshold?
4. How should the NTSB calculate the threshold value of ''substantial property damage''?
5. Should ''substantial property damage'' be based on total property damage, pipeline property damage, or non-pipeline property damage?
6. Should the dollar amount established be indexed for inflation?
7. Should ''substantial property damage'' consider factors other than monetary value?
8. Should the same definition apply to both municipality owned pipelines and publicly-traded company pipelines?
9. Should the NTSB define ''significant injury to the environment''?
10. Is the NTSB's proposed definition for ''significant injury to the environment'' sufficient?
11. How should the NTSB define ''significant injury to the environment''?
12. Should the NTSB's definition of ''significant injury to the environment'' be consistent with the PHMSA's definition of ''significant and substantial harm to the environment'' under 49 CFR 194.103(c)?

List of Subjects in 49 CFR Part 831

Aircraft accidents, Aircraft incidents, Aviation safety, Hazardous materials transportation, Highway safety, Investigations, Marine safety, Pipeline safety, Railroad safety.

William T. McMurry, Jr.,

General Counsel.

[FR Doc. 2023–18842 Filed 8–30–23; 8:45 am]

BILLING CODE 7533–01–P

Notices

Federal Register
Vol. 88, No. 168
Thursday, August 31, 2023

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

Farm Service Agency

[Docket ID: FSA–2023–0014]

Information Collection Requests; Disaster Assistance—General (0560–0170); Transfer of Farm Records Between Counties (0560–0253); Customer Data Worksheet Request for Business Partner Record Change (0560–0265)

AGENCY: Farm Service Agency, U.S. Department of Agriculture (USDA).

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) requirement, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on the three Farm Programs' information collection requests. The three collection requests in the Farm Programs are: Disaster Assistance—General (0560–0170), Transfer of Records between Counties (0560–0253) and Customer Data Worksheet Request for Business Partner Record (0560–0265). In the Disaster Assistance—General, the information collection is needed to identify disaster areas and establish eligibility for both primary disaster counties and those counties contiguous to such disaster counties for assistance from FSA. This assistance includes FSA emergency loans which are available to eligible and qualified farmers and ranchers. In the Customer Data Worksheet Request for Business Partner Record, FSA is using the collected information in support of documenting critical producer data (for example, customer name, current mailing address, tax identification number) made at the request of the producer to obtain, correct or update their information. In the Transfer of Records Between Counties, FSA is using the collected information to approve or disapprove the transfer of farm records from one FSA county office to another.

DATES: We will consider comments that we receive by October 30, 2023.

ADDRESSES: We invite you to submit comments in response to this notice. FSA prefers that the comments are submitted electronically through the Federal eRulemaking Portal, identified by Docket ID No. FSA–2023–0014, go to *http://www.regulations.gov* and search for docket ID FSA–2023–0014. Follow the online instructions for submitting comments. All comments received will be posted without change and made publicly available on *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to the collection activities or to obtain a copy of the information collection request: For the Disaster Assistance, please contact Helen Mathew, (202) 720–9878; *helen.mathew@usda.gov;* for the Customer Data Worksheet Request for Business Partner Record Change, and the Transfers of Records between Counties, please contact Tyler Gilkey, 402–437–5895, *tyler.gilkey@usda.gov.* Individuals who require alternative means for communication should 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:

Title: Disaster Assistance—General.

OMB Control Number: 0560–0170.

Expiration Date: December 31, 2023.

Type of Request: Extension.

Abstract: The information collection is necessary for FSA to effectively administer the regulations related to identifying those disaster areas that are eligible for the purpose of making emergency loans. This program is available to qualified and eligible farmers and ranchers who have suffered weather-related physical or production losses or both in such areas. Before emergency loans can become available, the information needs to be collected to determine if the disaster areas meet the criteria of having a qualifying loss in order to be considered as an eligible county.

There are no changes to the burden hours since the last OMB submission. For the following estimated total annual burden on respondents, the formula used to calculate the total burden hours is the estimated average time per response multiplied by the estimated total annual responses.

Estimate of Average Time to Respond: Public reporting burden for the information collection is estimated to average 0.477 hours per response.

Type of Respondents: Individuals or households, businesses or other for-profit farms.

Estimated Annual Number of Respondents: 1,312.

Estimated Number of Reponses per Respondent: 1.

Estimated Total Annual Responses: 1,312.

Estimated Total Annual Burden on Respondents: 626.

Title: Transfer of Farm Records between Counties.

OMB Control Number: 0560–0253.

Expiration Date: December 31, 2023.

Type of Request: Revision.

Abstract: Farm owners or operators may request to transfer farm records between FSA county offices under certain circumstances, which may include:

- A change has occurred in the operation of the land; or
- there has been a change that would cause the receiving county office to be more accessible, including, but not limited to, the construction of a new highway, relocation of the county office building site; or
- when an FSA county office closes.

FSA County Committees from both the transferring and receiving counties must approve or disapprove all proposed farm record transfers. If the FSA County Committee is not able to approve the request based on one of the criteria in 7 CFR 718.8, then the State Committee would need to submit an exception request to the Deputy Administrator for Farm Programs. The number of respondents and responses decreased by 13,701 while the burden hours decreased by 2,334 hours. The number of requests has decreased, likely in part due to the advancement of nationwide customer service and alignment of many farm programs to be based on physical location rather than administrative county. For the following estimated total annual burden on respondents, the formula used to calculate the total burden hours is the estimated average time per response

multiplied by the estimated total annual responses.

Estimated Respondent Burden: Public reporting burden for this collection of information is estimated to average 0.16 hours per response.

Type of Respondents: Owners and operators.

Estimated Number of Respondents: 7,539.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Number of Responses: 7,539.

Estimated Total Annual Burden on Respondents: 1,206 hours.

Title: Customer Data Worksheet Request for Business Partner Record Change.

OMB Control Number: 0560–0265.

Expiration Date: December 31, 2023.

Type of Request: Revision.

Abstract: The information collection is necessary to effectively monitor critical producer data (for example, customer name, current mailing address and tax identification number) made at the request of the producer to provide, correct or update their information. The form AD–2047, Customer Data Worksheet Request for Business Partner Record, is used to collect the information from the producer to input or make changes to the information. The critical producer data are also being used to update existing producer record data and document when and who initiates and changes the record. FSA, Natural Resource Conservation Service (NRCS) and other USDA Agencies use the Business Partner database to maintain and manage their respective customer data. The necessity to monitor critical producer data in the Business Partner database was a direct result of the OMB Circular A–123 Remediation/Corrective Action Plan for County Office Operations which requires effective internal controls to be in place for Federal programs. FSA team was established and reviewed and documented key controls related to all material producer accounts. FSA also included the analysis on a review of record. The number of respondents increased by 51,476 to account for additional customers due to additional USDA agencies. The average time per response is 3 minutes for the form of AD–2047. The burden hours increased by 2,674 in the request due to the increase in customer records added since the last OMB approval. For the following estimated total annual burden on respondents, the formula used to calculate the total burden hours is the estimated average time per response multiplied by the estimated total annual responses.

Estimated Respondent Burden: Public reporting burden for this collection of information is estimated to average 0.05 hours per response.

Type of Respondents: FSA, NRCS, AMS, and RD customers currently residing in the Business Partner database.

Estimated Number of Respondents: 161,250.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Number of Responses: 161,250.

Estimated Total Annual Burden on Respondents: 8,063 hours.

FSA is requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of FSA, including whether the information will have practical utility;

(2) Evaluate the accuracy of FSA's estimate of burden including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility and clarity of the information to be collected;

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and 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.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or 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). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410 or email: *OAC@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Steven Peterson,

Acting Administrator, Farm Service Agency.

[FR Doc. 2023–18828 Filed 8–30–23; 8:45 am]

BILLING CODE 3410–E2–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Foreign Agricultural Service (FAS) to request an extension from the Office of Management and Budget (OMB) of a currently approved information collection in support of the foreign donation of agricultural commodities under the section 416(b) program, the Food for Progress Program, and the McGovern-Dole International Food for Education and Child Nutrition Program.

DATES: Comments on this notice must be received by October 30, 2023.

ADDRESSES: You may send comments by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* This portal

enables respondents to enter short comments or attach a file containing lengthier comments.

• *Email: Shane.Danielson@USDA.gov.* Include OMB Control Number 0551–0035 in the subject line of the message.

• *Mail, Courier, or Hand Delivery:* Shane Danielson, Senior Director, International Food Assistance Division, Foreign Agricultural Service, U.S. Department of Agriculture, Stop 1034, Washington, DC 20250–1034.

Instructions: All submissions must be identified by the OMB Control Number 0551–0035 and include the name of the agency, the Foreign Agricultural Service.

FOR FURTHER INFORMATION CONTACT: Shane Danielson, Senior Director, International Food Assistance Division, Foreign Agricultural Service, U.S. Department of Agriculture, Stop 1034, Washington, DC 20250–1034; or by email at *Shane.Danielson@USDA.gov;* or by telephone at (202) 720–1230.

SUPPLEMENTARY INFORMATION:

Title: Foreign Donation of Agricultural Commodities (section 416(b) and Food for Progress programs) and McGovern-Dole International Food for Education and Child Nutrition Program.

OMB Number: 0551–0035.

Expiration Date of Approval: April 30, 2024.

Type of Request: Extension of a currently approved information collection.

Abstract: Under the section 416(b) and Food for Progress programs (the ''Foreign Donation Programs'') and the McGovern-Dole International Food for Education and Child Nutrition (''McGovern-Dole'') Program, information will be gathered from applicants desiring to receive federal awards under the programs to determine the viability of requests for resources to implement activities in foreign countries. Recipients of awards under the programs must submit compliance reports and other information until activities carried out with donated commodities or funds, or local currencies generated from the sale of donated commodities, are completed. Recipients that use the services of freight forwarders must submit certifications from the freight forwarders regarding their activities and affiliations. Documents are used to develop effective grant and cooperative agreements for awards under the programs and assure that statutory requirements and objectives are met.

Estimate of Burden: The public reporting burden for each respondent resulting from information collections under the Foreign Donation Programs or the McGovern-Dole Program varies in direct relation to the number and type of agreements entered into by such respondent. The estimated average reporting burden for the Foreign Donation Programs is 45.74 hours per response and for the McGovern-Dole Program is 45.74 hours per response.

Respondents: Private voluntary organizations, cooperatives, colleges and universities, foreign governments, intergovernmental organizations, freight forwarders, ship owners and brokers, and survey companies.

Estimated Number of Respondents: 61 per annum.

Estimated Number of Responses per Respondent: 32 per annum.

Estimated Total Annual Burden: 89,284.5 hours.

Copies of this information collection may be obtained from Dacia Rogers, the Agency Information Collection Coordinator, at *Dacia.Rogers@usda.gov.*

Request for Comments: Send comments regarding (a) whether the information to be collected is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be made available without change, including any personal information provided, for inspection online at *http://www.regulations.gov* and at 1400 Independence Avenue SW, Room 6648, Washington, DC 20250, between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays. Comments will be summarized and included in the submission for OMB approval.

Persons with disabilities who require an alternative means for communication of information (Braille, large print, audiotape, etc.) should contact *RARequest@usda.gov.*

Daniel Whitley,

Administrator, Foreign Agricultural Service.

[FR Doc. 2023–18773 Filed 8–30–23; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Assessment of Fees for Dairy Import Licenses for the 2024 Tariff-Rate Import Quota Year

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces a fee of $350 to be charged for the 2024 tariff-rate quota (TRQ) year for each license issued to a person or firm by the Department of Agriculture authorizing the importation of certain dairy articles, which are subject to tariff-rate quotas set forth in the Harmonized Tariff Schedule (HTS) of the United States.

DATES: This notice is applicable on August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Elizabeth Riley, Dairy Import Licensing Program, Foreign Agricultural Service, U.S. Department of Agriculture, at (202) 720–6868; or by email at: *Elizabeth.riley@usda.gov.*

SUPPLEMENTARY INFORMATION: The Dairy Tariff-Rate Quota Import Licensing Regulation promulgated by the Department of Agriculture and codified at 7 CFR 6.20–6.36 provides for the issuance of licenses to import certain dairy articles that are subject to TRQs set forth in the HTS. Those dairy articles may only be entered into the United States at the in-quota TRQ tariff-rates by or for the account of a person or firm to whom such licenses have been issued and only in accordance with the terms and conditions of the regulation.

Licenses are issued on a calendar year basis, and each license authorizes the license holder to import a specified quantity and type of dairy article from a specified country of origin. The use of such licenses is monitored by the Import Program within the Foreign Agricultural Service, U.S. Department of Agriculture, and U.S. Customs and Border Protection, U.S. Department of Homeland Security.

The regulation at 7 CFR 6.33(a) provides that a fee will be charged for each license issued to a person or firm by the Licensing Authority to defray the Department of Agriculture's costs of administering the licensing system under this regulation.

The regulation at 7 CFR 6.33(a) also provides that the Licensing Authority will announce the annual fee for each license and that such fee will be set out in a notice to be published in the **Federal Register**. Accordingly, this notice sets out the fee for the licenses to be issued for the 2024 calendar year.

The total cost to the Department of Agriculture of administering the licensing system for 2024 has been estimated to be $936,025.00 and the estimated number of licenses expected to be issued is 2,674. Of the total cost, $503,619.00 represents staff and supervisory costs directly related to administering the licensing system, and $432,406.00 represents other miscellaneous costs, including travel, publications, forms, and Automatic Data Processing (ADP) system support.

Accordingly, notice is hereby given that the fee for each license issued to a person or firm for the 2024 calendar year, in accordance with 7 CFR 6.33, will be $350 per license.

Aileen Mannix,

Acting Licensing Authority, Foreign Agricultural Service.

[FR Doc. 2023–18901 Filed 8–30–23; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Adjustment of Appendices Under the Dairy Tariff-Rate Quota Import Licensing Regulation

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the transfer of amounts for certain dairy articles from the historical license category (Appendix 1) to the lottery (nonhistorical) license category (Appendix 2) pursuant to the Dairy Tariff-Rate Quota Import Licensing regulations for the 2023 quota year.

DATES: August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Elizabeth Riley, (202) 720–6868, *Elizabeth.riley@usda.gov.*

SUPPLEMENTARY INFORMATION: The Foreign Agricultural Service, under a delegation of authority from the Under Secretary for Trade and Foreign Agricultural Affairs, administers the Dairy Tariff-Rate Import Quota Licensing Regulation codified at 7 CFR 6.20–6.36 that provides for the issuance of licenses to import certain dairy articles under tariff-rate quotas (TRQs) as set forth in the Harmonized Tariff Schedule (HTS) of the United States. These dairy articles may only be entered into the United States at the low-tier tariff by or for the account of a person or firm to whom such licenses have been issued and only in accordance with the terms and conditions of the regulation.

Licenses are issued on a calendar year basis, and each license authorizes the license holder to import a specified quantity and type of dairy article from a specified country of origin. The Imports Program, Foreign Agricultural Service, U.S. Department of Agriculture, issues these licenses and, in conjunction with U.S. Customs and Border Protection, U.S. Department of Homeland Security, monitors their use.

The regulation at 7 CFR 6.34(a) states that whenever a historical license (Appendix 1) is permanently surrendered, revoked by the Licensing Authority, or not issued to an applicant pursuant to the provisions of § 6.23, then the amount of such license will be transferred to Appendix 2. Section 6.34(b) provides that the cumulative annual transfers will be published by notice in the **Federal Register**. Accordingly, this document sets forth the revised Appendices in the table below. Although there are no changes to the quantities for designated licenses (Appendix 3 and Appendix 4), those numbers are also included in the table below for completeness.

Aileen Mannix,

Acting Licensing Authority, Foreign Agricultural Service.

ARTICLES SUBJECT TO DAIRY IMPORT LICENSES

[Kilograms] [1]

	Historical licenses (appendix 1) [2]	Lottery licenses (appendix 2) [3]	Sum of appendix 1 & 2 [4]	Designated licenses (Tokyo round, appendix 3) [4]	Designated licenses (Uruguay round, appendix 4) [4]	Total [4]
NON-CHEESE ARTICLES, Notes 6, 7, 8, 12, 14 (Appendix 1 reduction):						
Butter (Note 6, Commodity Code G)	4,200,466	2,776,534	6,977,000			6,977,000
EU–27	53,445	28,654	82,099			
New Zealand	76,503	74,090	150,593			
United Kingdom	7,144	6,918	14,062			
Other Countries	31,863	42,072	73,935			
Any Country	4,031,511	2,624,800	6,656,311			
Dried Skim Milk (Note 7, Commodity Code K)	0	5,261,000	5,261,000			5,261,000
Australia	0	600,076	600,076			
Canada	0	219,565	219,565			
Any Country	0	4,441,359	4,441,359			
Dried Whole Milk (Note 8, Commodity Code H)	0	3,321,300	3,321,300			3,321,300
New Zealand	0	3,175	3,175			
Any Country	0	3,318,125	3,318,125			
Dried Buttermilk/Whey (Note 12, Commodity Code M)	0	224,981	224,981			224,981
Canada	0	161,161	161,161			
New Zealand	0	63,820	63,820			
Butter Substitutes Containing Over 45 Percent of Butterfat and/or Butter Oil (Note 14, Commodity Code SU)	0	6,080,500	6,080,500			6,080,500
Any Country	0	6,080,500	6,080,500			
Total: Non-Cheese Articles	4,200,466	17,664,315	21,864,781			21,864,781
Cheese Articles (Notes 16, 17, 18, 19, 20, 21, 22, 23, 25):						

ARTICLES SUBJECT TO DAIRY IMPORT LICENSES—Continued

[Kilograms] [1]

	Historical licenses (appendix 1) [2]	Lottery licenses (appendix 2) [3]	Sum of appendix 1 & 2 [4]	Designated licenses (Tokyo round, appendix 3) [4]	Designated licenses (Uruguay round, appendix 4) [4]	Total [4]
Cheese and Substitutes for Cheese (Note 16, Commodity Code OT) (−346,844 kg)	16,536,559	14,933,172	31,469,731	9,661,128	7,496,000	48,626,859
Argentina	0	7,690	7,690	92,310	.....	100,000
Australia	13,122	528,048	541,170	758,830	1,750,000	3,050,000
Canada	882,039	258,961	1,141,000	.....	.....	1,141,000
Costa Rica	0	0	0	.....	1,550,000	1,550,000
EU–27 (not including Portugal) (−136,766 kg)	12,566,115	8,709,452	21,275,567	835,707	3,168,576	25,279,850
Portugal	65,838	63,471	129,309	223,691	.....	353,000
Israel	79,696	0	79,696	593,304	.....	673,000
Iceland	29,054	0	294,000	29,000	.....	323,000
New Zealand	1,314,690	3,500,782	4,815,472	6,506,528	.....	11,322,000
Norway	122,860	27,140	150,000	.....	.....	150,000
Switzerland	505,880	165,532	671,412	548,588	500,000	1,720,000
Uruguay	0	0	0	.....	250,000	250,000
United Kingdom (−210,078 kg)	875,138	987,642	1,862,780	73,170	277,424	2,213,374
Other Countries	82,127	119,508	201,635	.....	.....	201,635
Any Country	0	300,000	300,000	.....	.....	300,000
Blue-Mold Cheese (Note 17, Commodity Code B) (−3,324 kg)	1,919,656	561,345	2,481,001	.....	430,000	2,911,001
Argentina	2,000	0	2,000	.....	.....	2,000
EU–27 (−2,941 kg)	1,905,316	552,989	2,458,305	.....	347,078	2,805,383
Chile	0	0	0	.....	80,000	80,000
United Kingdom (−383 kg)	12,340	8,355	20,695	.....	2,922	23,617
Other Countries	0	1	1	.....	.....	1
Cheddar Cheese (Note 18, Commodity Code C) (−10,749 kg)	2,245,742	2,038,114	4,283,856	519,033	7,620,000	12,422,889
Australia (−4,676 kg)	867,866	116,633	984,499	215,501	1,250,000	2,450,000
Chile	0	0	0	0	220,000	220,000
EU–27 (−1,513 kg)	12,106	71,431	83,537	0	333,515	417,052
New Zealand (−4,560 kg)	1,260,510	1,535,958	2,796,468	303,532	5,100,000	8,200,000
United Kingdom	26,006	153,457	179,463	0	716,485	895,948
Other Countries	79,254	60,635	139,889	.....	.....	139,889
Any Country	0	100,000	100,000	.....	.....	100,000
American-Type Cheese (Note 19, Commodity Code A) (−12,766 kg)	1,124,658	2,040,895	3,165,553	357,003	0	3,522,556
Australia (−3,696 kg)	744,943	136,055	880,998	119,002	.....	1,000,000
EU–27	131,539	222,461	354,000	.....	.....	354,000
New Zealand (−9,070 kg)	145,120	1,616,879	1,761,999	238,001	.....	2,000,000
Other Countries	103,056	65,500	168,556	.....	.....	168,556
Edam and Gouda Cheese (Note 20, Commodity Code D) (−8,629 kg)	4,230,506	1,375,896	5,606,402	0	1,210,000	6,816,402
Argentina	105,418	19,582	125,000	.....	110,000	235,000
EU–27 (−8,629 kg)	4,009,280	1,279,720	5,289,000	.....	1,100,000	6,389,000
Norway	111,046	55,954	167,000	.....	.....	167,000
Other Countries	4,762	20,640	25,402	.....	.....	25,402
Italian-Type Cheeses (Note 21, Commodity Code D) (−2,288 kg)	5,824,262	1,696,285	7,520,547	795,517	5,165,000	13,481,064
Argentina	3,507,548	617,935	4,125,483	367,517	1,890,000	6,383,000
EU–27 (−2,288 kg)	2,316,714	1,065,286	3,382,000	.....	2,025,000	5,407,000
Romania	0	0	0	.....	500,000	500,000
Uruguay	0	0	0	428,000	750,000	1,178,000
Other Countries	0	13,064	13,064	.....	.....	13,064
Swiss or Emmenthaler Cheese (Note 22, Commodity Code GR) (−4,546 kg)	3,378,368	3,272,946	6,651,314	823,519	380,000	7,854,833
EU–27 (−4,546 kg)	2,155,902	2,996,092	5,151,994	393,006	380,000	5,925,000
Switzerland	1,211,306	208,181	1,419,487	430,513	.....	1,850,000
Other Countries	11,160	68,673	79,833	.....	.....	79,833
Lowfat Cheese (Note 23, Commodity Code LF)	1,173,766	3,251,142	4,424,908	1,050,000	0	5,474,908
EU–27	1,173,766	3,251,141	4,424,907	.....	.....	4,424,907
Israel	0	0	0	50,000	.....	50,000
New Zealand	0	0	0	1,000,000	.....	1,000,000
Other Countries	0	1	1	.....	.....	1
Swiss or Emmenthaler Cheese With Eye Formation (Note 25, Commodity Code SW) (−9,092 kg)	12,855,263	9,442,068	22,297,331	9,557,945	2,620,000	34,475,276
Argentina	0	9,115	9,115	70,885	.....	80,000
Australia	209,698	0	209,698	290,302	.....	500,000
Canada	0	0	0	70,000	.....	70,000
EU–27 (−9,092 kg)	9,635,502	6,841,326	16,476,828	4,003,172	2,420,000	22,900,000
Iceland	0	149,999	149,999	150,001	.....	300,000
Israel	0	27,000	27,000	.....	.....	27,000
Norway	2,207,873	1,447,437	3,655,310	3,227,690	.....	6,883,000
Switzerland	759,369	924,736	1,684,105	1,745,895	200,000	3,630,000
Other Countries	42,821	42,455	85,276	.....	.....	85,276
Total: Cheese Articles (−398,238 kg)	49,288,780	38,611,863	87,900,643	22,764,145	24,921,000	135,585,788

ARTICLES SUBJECT TO DAIRY IMPORT LICENSES—Continued

[Kilograms] [1]

	Historical licenses (appendix 1) [2]	Lottery licenses (appendix 2) [3]	Sum of appendix 1 & 2 [4]	Designated licenses (Tokyo round, appendix 3) [4]	Designated licenses (Uruguay round, appendix 4) [4]	Total [4]
Total: Cheese & Non-Cheese	53,489,246	56,276,178	109,765,424	22,764,145	24,921,000	157,450,569

[1] Source of the total TRQs is the U.S. Harmonized Tariff Schedule, Chapter 4, in the corresponding Additional U.S. Notes.
[2] Reduced from 2022 by a total of -398,238 kg.
[3] Increased from 2022 by a total of 398,238 kg.
[4] No change.

[FR Doc. 2023–18900 Filed 8–30–23; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

Notice of Intent To Extend and Revise a Currently Approved Information Collection

AGENCY: National Institute of Food and Agriculture, U.S. Department of Agriculture (USDA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, this notice announces the National Institute of Food and Agriculture's (NIFA) intention to extend and revise a currently approved information collection entitled, ''Reporting Requirements for State Plans of Work for Agricultural Research and Extension Formula Funds.'' NIFA is proposing to change the collection title to ''NIFA Reporting System (NRS)'', include a new financial reporting module, modify existing reports in order to request digital persistent identifiers, and allow respondents to provide information on Co-Project Director(s) when applicable.

DATES: Written comments on this notice must be received by October 30, 2023 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: You may submit comments through the Federal eRulemaking Portal: *www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All comments received will be posted without change to *www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Laura Givens, 816–527–5379, *Laura.Givens@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: NIFA Reporting System (NRS).

OMB Control Number: 0524–0036.

Expiration Date of Current Approval: 10/31/2025.

Type of Request: Notice of intent to extend and revise a currently approved information collection.

Abstract: The ''NIFA Reporting System'' (NRS), provides data management and reporting for capacity funded research projects and extension programs. NRS currently contains the Agricultural Research, Extension, and Education Reform Act of 1998 (AREERA) (7 U.S.C. 7601 *et seq.*) Plans of Work, Annual Reports of Accomplishments, and other capacity grant data for research projects and extension programs. The programs are authorized pursuant to the authorities contained in the McIntire-Stennis Cooperative Forestry Act of 1962 (16 U.S.C. 582a *et seq.*), the Hatch Act of 1887 and the Hatch Multistate Research Fund (7 U.S.C. 361a and 361c), the Agricultural Extension at 1890 Land-Grant Institutions (7 U.S.C. 3221), Agricultural research at 1890 land-grant colleges (7 U.S.C. 3222), Animal Health and Disease Research (7 U.S.C. 3195), Renewable Resources Extension Act of 1978 (16 U.S.C. 1674), District of Columbia Public Post-secondary Education Reorganization Act (DC ST Section 38–1202.09), and the Smith-Lever Act (7 U.S.C. 341).

NIFA proposes to add a new financial module within NRS comprised of two separate forms: the Financial Report form and the Office of Grants and Financial Management (OGFM) supplemental information form.

The Financial Report form will capture expenditures for individual research projects and extension programs and will allow for both individual and bulk data entry options. This reporting would include NIFA, other federal, state, and other funding expenditures and Full Time Equivalents (FTE) supporting the project/program during the fiscal year of reporting.

The OGFM Supplemental Information Form will collect information on required target percentages for integrated and extension programs required to submit this information as part of AREERA reporting requirements. NIFA plans to prepopulate some of the fields in the form so that the response will be limited to total expenditures of three types (Hatch (Regular and Multistate) integrated, Smith-Lever multistate, and Smith-Lever extension activities), any carryover used, and information for a waiver (if applicable).

NIFA also proposes to modify the Project/Program Initiation report to include a new optional field for Co-Project Directors.

Finally, NIFA also seeks to modify the Project/Program Results report to include a new field for digital persistent identifiers associated with products resulting from capacity funded research projects and extension programs.

Total Estimate of the Burden: The estimated annual reporting burden for the NRS collection is as follows:

I. Plan of Work

The total annual estimated burden for this information collection is 4,800 hours. This includes the time needed for participant education; data entry, aggregation, and reporting; and preparation, review, and submission of program plans and budgetary information. There are four components of the Plan of Work: Executive Summary, Merit and Scientific Peer Review Processes, Stakeholder Input, and Critical Issues.

Estimate of Burden:

Estimated Number of Respondents: 75 per year.

Estimated Number of Responses per Respondent: 1.

Estimated Burden per Response: 64 hours.

Estimated Total Annual Burden on Respondents: 4,800 hours.

Frequency of Responses: Annually.

II. Annual Report of Accomplishments and Results

The total annual estimated burden for this information collection is 4,800 hours. This includes the time needed for participant education; data entry,

aggregation, and reporting; and preparation, review, and submission of program plans and budgetary information.

Estimated Number of Respondents: 75 per year.

Estimated Number of Responses per Respondent: 1.

Estimated Burden per Response: 64 hours.

Estimated Total Annual Burden on Respondents: 4,800 hours.

Frequency of Responses: Annually.

III. Project/Program Initiation

The total annual estimated burden for this information collection is 9,200 hours. This includes the time needed for participant education; data entry, aggregation, and reporting; and preparation, review, and submission of program plans and budgetary information. NIFA proposes to add a new optional field for Co-Project Director(s) but anticipates that this will not increase the amount of time needed to complete each response.

Estimated Number of Respondents: 2,000 per year.

Estimated Number of Responses per Respondent: 1.

Estimated Burden per Response: 4.6 hours.

Estimated Total Annual Burden on Respondents: 9,200 hours.

Frequency of Responses: Annually.

IV. Project/Program Results

The total annual estimated burden for this information collection is 32,300 hours. This includes the time needed for participant education; data entry, aggregation, and reporting; and preparation, review, and submission of program plans and budgetary information. Project/Program Results were previously included in ''Annual Report of Accomplishments and Results'' above but is being separated to include Results for non-AREERA capacity funding. NIFA is proposing to add fields specifically for reporting products resulting from projects and programs but anticipates that this will not increase the amount of time needed to complete each response.

Estimated Number of Respondents: 8,500 per year.

Estimated Number of Responses per Respondent: 1.

Estimated Burden per Response: 3.8 hours.

Estimated Total Annual Burden on Respondents: 32,300 hours.

Frequency of Responses: Annually.

V. Financial Report for All Projects and Programs

The total annual estimated burden for this information collection is 11,900 hours. This includes the time needed for participant education; data entry, aggregation, and reporting; and preparation, review, and submission of program plans and budgetary information. NIFA used burden estimates from the Financial Report in the current REEport collection (OMB 0524–0048, ''Research, Education, and Extension project online reporting tool (REEport)'') to estimate the burden for Financial Report in NRS.

Estimated Number of Respondents: 8,500 per year.

Estimated Number of Responses per Respondent: 1.

Estimated Burden per Response: 1.4 hours.

Estimated Total Annual Burden on Respondents: 11,900 hours.

Frequency of Responses: Annually.

VI. OGFM Supplemental Form

The total annual estimated burden for this information collection is 102 hours. This includes the time needed for participant education; data entry, aggregation, and reporting; and preparation, review, and submission of program plans and budgetary information. NIFA plans to prepopulate some of the fields in the form so that the response will be limited to total expenditures of three types (Hatch (Regular and Multistate) integrated, Smith-Lever multistate, and Smith-Lever extension activities), any carryover used, and information for a waiver (if applicable). The OGFM Supplemental Form will have a deadline after the Financial Report, which should streamline the expenditures data needed.

Estimated Number of Respondents: 51 per year.

Estimated Number of Responses per Respondent: 1.

Estimated Burden per Response: 2 hours.

Estimated Total Annual Burden on Respondents: 102 hours.

Frequency of Responses: Annually.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will 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 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 are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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.

Obtaining a Copy of the Information Collection: A copy of the information collection and related instructions may be obtained free of charge by contacting Laura Givens as directed above.

Done at Washington, DC, this day of August 19, 2023.

Dionne Toombs,

Associate Director for Programs, National Institute of Food and Agriculture, U.S. Department of Agriculture.

[FR Doc. 2023–18852 Filed 8–30–23; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Mississippi Trustee Implementation Group Deepwater Horizon Oil Spill Draft Restoration Plan 4 and Environmental Assessment: Restoration of Wetlands, Coastal and Nearshore Habitats; Nutrient Reduction (Nonpoint Source); and Provide and Enhance Recreational Opportunities

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture (USDA).

ACTION: Notice of availability; request for public comments.

SUMMARY: In accordance with the Oil Pollution Act of 1990 (OPA), the National Environmental Policy Act of 1969 (NEPA), the Deepwater Horizon (DWH) Oil Spill Final Programmatic Damage Assessment Restoration Plan and Final Programmatic Environmental Impact Statement and Record of Decision, and the Consent Decree, the Federal and State natural resource trustee agencies for the Mississippi Trustee Implementation Group (MS TIG) have prepared the ''Mississippi Trustee Implementation Group Draft Restoration Plan 4 and Environmental Assessment: Restoration of Wetlands, Coastal, and Nearshore Habitats; Nutrient Reduction (Nonpoint Source), and Provide and Enhance Recreational Opportunities'' (Draft RP4 and EA). In the Draft RP4 and EA, MS TIG proposes projects to partially restore wetlands, coastal, and nearshore habitats; reduce nutrient pollution (nonpoint source); and provide and enhance recreational opportunities to compensate for lost

recreational use in the Mississippi Restoration Area as a result of the DWH oil spill. The Draft RP4 and EA, a No Action alternative is also evaluated for each of the restoration types. The approximate cost to implement the MS TIG's proposed action (seven preferred alternatives) is $26.4 million. We invite public comments on the Draft RP4 and EA.

DATES: We will consider comments that we receive by October 2, 2023.

ADDRESSES: *Obtaining Documents:* You may download the Draft RP4 and EA from the following website: *https://www.gulfspillrestoration.noaa.gov/restoration-areas/mississippi.*

Alternatively, you may request a CD of the Draft RP4 and EA (see **FOR FURTHER INFORMATION CONTACT**).

Submitting Comments: You may submit comments by one of the following methods:

- *Via the Web: http://www.gulfspillrestoration.noaa.gov/restoration-areas/mississippi;* or
- *Via U.S. Mail:* U.S. Fish and Wildlife Service, 1875 Century Boulevard, Atlanta, GA 30345.

FOR FURTHER INFORMATION CONTACT: Nanciann Regaldo, *Nanciann_regalado@fws.gov,* 678–296–6805, or via the Federal Relay Service at 800–877–8339; Ronald Howard, Senior Advisor, USDA Gulf Coast Ecosystem Restoration Team, at *ron.howard@usda.gov;* and Dr. Tina Nations, the Natural Resource Damage Assessment (NRDA) and the National Fish and Wildlife Foundation Program Manager, MDEQ Office of Restoration, *tnations@mdeq.ms.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

On April 20, 2010, the mobile offshore drilling unit Deepwater Horizon, which was being used to drill well for BP Exploration and Production, Inc. (BP), in the Macondo prospect (Mississippi Canyon 252–MC252), experienced a significant explosion, fire, and subsequent sinking in the Gulf of Mexico, resulting in an unprecedented volume of oil and other discharges from the rig and from the wellhead on the seabed. The DWH oil spill is the largest offshore oil spill in U.S. history, discharging millions of barrels of oil over a period of 87 days. In addition, well over 1 million gallons of dispersants were applied to the waters of the spill area in an attempt to disperse the spilled oil. An undetermined amount of natural gas was also released into the environment as a result of the spill.

The DWH Federal and State natural resource trustees (DWH Trustees) conducted NRDA for the DWH oil spill under OPA (33 U.S.C. 2701–2720). Pursuant to OPA, Federal, and State agencies act as trustees on behalf of the public to assess natural resource injuries and losses and to determine the actions required to compensate the public for those injuries and losses. OPA further instructs the designated trustees to develop and implement a plan for the restoration, rehabilitation, replacement, or acquisition of the equivalent of the injured natural resources under their trusteeship to baseline (the resource quality and conditions that would exist if the spill had not occurred). This includes the loss of use and services provided by those resources from the time of injury until the completion of restoration.

The DWH Trustees are:

- U.S. Department of the Interior (DOI), as represented by the National Park Service, U.S. Fish and Wildlife Service, and Bureau of Land Management;
- National Oceanic and Atmospheric Administration (NOAA), on behalf of the U.S. Department of Commerce;
- USDA;
- U.S. Environmental Protection Agency (EPA);
- State of Louisiana Coastal Protection and Restoration Authority, Oil Spill Coordinator's Office, Department of Environmental Quality, Department of Wildlife and Fisheries, and Department of Natural Resources;
- State of Mississippi Department of Environmental Quality;
- State of Alabama Department of Conservation and Natural Resources and Geological Survey of Alabama;
- State of Florida Department of Environmental Protection and Fish and Wildlife Conservation Commission; and
- State of Texas: Texas Parks and Wildlife Department, Texas General Land Office, and Texas Commission on Environmental Quality.

On April 4, 2016, the United States District Court for the Eastern District of Louisiana entered a Consent Decree resolving civil claims by the DWH Trustees against BP arising from the DWH oil spill: *United States* v. *BPXP et al.,* Civ. No. 10–4536, centralized in MDL 2179, In re: Oil Spill by the Oil Rig ''Deepwater Horizon'' in the Gulf of Mexico, on April 20, 2010 (E.D. La.) (*http://www.justice.gov/enrd/deepwater-horizon*). Pursuant to the Consent Decree, restoration projects in the Mississippi Restoration Area are chosen and managed by MS TIG. MS TIG is composed of the following Trustees: State of Mississippi Department of Environmental Quality; DOI; NOAA; EPA; and USDA.

On February 7, 2022, MS TIG posted a public notice requesting natural resource restoration project ideas by March 7, 2022, for the Mississippi Restoration Area. The notice stated that MS TIG was seeking project ideas for the following restoration types:

(1) Wetlands, Coastal, and Nearshore Habitat;

(2) Nutrient Reduction; and

(3) Provide and Enhance Recreational Opportunities.

On October 11, 2022, MS TIG announced that it had initiated drafting of the RP4 and EA (*https://www.gulfspillrestoration.noaa.gov/2022/10/notice-initiation-restoration-planning-mississippi*) and that the plan may include proposed projects for some or all of the three restoration types.

Overview of the MS TIG Draft RP4 and EA

The Draft RP4 and EA provides the MS TIG's analysis of a reasonable range of restoration alternatives. The MS TIG's seven preferred alternatives are presented in the following table under the restoration type from which funds would be allocated in accordance with the DWH Consent Decree. The MS TIG also evaluated three non-preferred alternatives as part of the reasonable range, and a No Action alternative for each restoration type in the plan.

Restoration Type: Wetlands, Coastal and Nearshore Habitat

Coastwide Habitat Acquisition
Living Shoreline Bulkhead Alternative
Hancock County Marsh Living Shoreline Phase 6 Breakwater

Restoration Type: Nutrient Reduction (Nonpoint Source)

Back Bay—Davis Bayou Nutrient Reduction
Big Cedar Creek—Rocky Creek Nutrient Reduction

Restoration Type: Provide and Enhance Recreational Opportunities

Jourdan River Boardwalk
Shepard State Park Recreational Enhancements—1

Next Steps

MS TIG will post a pre-recorded public webinar to facilitate the public review and comment process no later than September 15, 2023. The pre-recorded webinar will be available on the Mississippi Department of Environmental Quality Office of Restoration website at *https://www.mdeq.ms.gov/restoration/.* The pre-recorded public webinar will be available for viewing at any time during the public comment period.

After the public comment period ends, the MS TIG will consider all comments received and address them in the Final RP4 and EA.

Public Availability of Comments

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.

Translation Opportunities

Vietnamese and Spanish translated materials including the Executive Summary and project fact sheets are posted in the ''News'' section of the MS TIG website: *http://www.gulfspillrestoration.noaa.gov/restoration-areas/mississippi.*

Administrative Record

The documents comprising the Administrative Record for the Draft RP4 and EA can be viewed electronically at *https://www.doi.gov/deepwaterhorizon/adminrecord* under the folder 6.5.6.2.4.

Authority

The authority for this action is OPA, its implementing NRDA regulations in 15 CFR part 990, and NEPA (42 U.S.C. 4321–4347) and its implementing regulations in 40 CFR 1500–1508.

Ronald Howard,

Senior Technical Advisor, Natural Resource Specialist, Natural Resources Conservation Service, and U.S. Department of Agriculture, Alternate to Principal Representative.

[FR Doc. 2023–18774 Filed 8–30–23; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

[Docket No. RHS–23–CF–0009]

Announcement of the Availability of Fiscal Year 2023 Disaster Relief Supplemental Grant Funds for the Community Facilities Technical Assistance and Training Grant Program for Fiscal Year 2023

AGENCY: Rural Housing Service, USDA.

ACTION: Notice of funding of availability (NOFA).

SUMMARY: The Rural Housing Service (RHS or the Agency), a Rural Development (RD) agency of the United States Department of Agriculture (USDA), announces that it is accepting applications under the Consolidated Appropriations Act, 2023, for the Community Facilities Technical Assistance and Training Disaster Repair Grant Program to provide technical assistance for repairing essential community facilities damaged by Presidentially declared disasters in calendar year 2022. The funding amount is up to $2,500,000 and will remain available until expended. The grant funds will be administered in accordance with this notice of funding availability and all applicable statutory and regulatory requirements of the Community Facilities Technical Assistance and Training (CF TAT) Grant Program.

DATES: Complete applications for grants must be submitted according to the following deadlines:

Paper submissions: Paper submissions must be received by the Agency no later than 4:00 p.m. local time on November 29, 2023 to be eligible for funding under this grant opportunity. Late or incomplete applications will not be eligible for funding.

Electronic submissions: Electronic applications will be accepted via *Grants.gov*. The deadline for receipt of an electronic application via *Grants.gov* is 11:59 p.m. Eastern Time on November 24, 2023. The application dates and times are firm. The Agency will not consider any application received after the deadline. To submit an electronic application, follow the instructions for the CF TAT Disaster Repair Grant Program funding announcement located at *http://www.grants.gov*.

Prior to official submission of applications, applicants may request technical assistance or other application guidance from the Agency, as long as such requests are made prior to November 14, 2023. Technical assistance is not meant to be an analysis or assessment of the quality of the materials submitted, a substitute for agency review of completed applications, nor a determination of eligibility, if such determination requires in-depth analysis. The Agency will not solicit or consider scoring or eligibility information that is submitted after the application deadline. The Agency reserves the right to contact applicants to seek clarification information on materials contained in the submitted application.

ADDRESSES: This funding announcement will be announced on *www.Grants.gov*. *Paper a*pplications must be submitted to the USDA Rural Development State Office (RDSO) for the State where the Applicant is headquartered. For Projects involving multiple states, the application must be filed in the RDSO where the Applicant is located. Applicants are encouraged to contact their respective RDSO for an address to submit an application prior to the submission deadline date. Applicants may also request paper application packages from their respective RDSO. A list of the USDA RDSO contacts can be found at: *https://www.rd.usda.gov/about-rd/state-offices.*

Entities applying for assistance may download the application documents and requirements delineated in this notice from: *https://www.Grants.gov.* Application information for electronic submissions may be found at *http://www.Grants.gov.*

FOR FURTHER INFORMATION CONTACT: Nathan Chitwood, Special Projects Coordinator at email address *nathan.chitwood@usda.gov,* United States Department of Agriculture, Rural Development, Business Loop 70 West, Suite 235, Columbia, MO 65203; or via telephone at: 573–876–0965. For further information on submitting program applications under this notice, please contact the USDA RDSO in the state where the applicant's headquarters is located. A list of RDSO contacts is provided at the following link: *https://www.rd.usda.gov/about-rd/state-offices.*

SUPPLEMENTARY INFORMATION:

Overview

Federal Awarding Agency Name: Rural Housing Service (RHS).

Funding Opportunity Title: Community Facilities Technical Assistance and Training Disaster Repair Grant.

Announcement Type: Notice of Funding of Availability (NOFA).

Funding Opportunity Number: USDA–RD–CFDTAT–2023.

Assistance Listing: 10.766.

Dates: Applications must be submitted using one of the following methods:

- *Paper submissions:* The deadline for receipt of a paper application is 4:00 p.m. local time, November 29, 2023. Applicants intending to mail applications must provide sufficient time to permit delivery on or before the closing deadline date and time. Acceptance by the United States Postal Service or private mailer does not constitute delivery. Facsimile (FAX), electronic mail, and postage due applications will not be accepted.
- *Electronic submissions:* Electronic applications will be accepted via *Grants.gov*. The deadline for receipt of an electronic application via *Grants.gov*

is 11:59 p.m. Eastern Time on November 24, 2023. The application dates and times are firm. The Agency will not consider any application received after the deadline.

Prior to official submission of applications, applicants may request technical assistance or other application guidance from the Agency, as long as such requests are made prior to November 14, 2023. Technical assistance is not meant to be an analysis or assessment of the quality of the materials submitted, a substitute for agency review of completed applications, nor a determination of eligibility, if such determination requires in-depth analysis. The Agency will not solicit or consider scoring or eligibility information that is submitted after the application deadline. The Agency reserves the right to contact applicants to seek clarification information on materials contained in the submitted application.

Rural Development Key Priorities: The Agency encourages applicants to consider projects that will advance the following key priorities (more details available at *https://www.rd.usda.gov/priority-points*):

- Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.
- Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects; and
- Assisting rural communities recover economically through more and better market opportunities and through improved infrastructure.

For further information, visit *https://www.rd.usda.gov/priority-points.*

A. Program Description

1. *Purpose of the Program.* The purpose of the CF TAT Disaster Repair Grant Program is to provide technical assistance and training with respect to essential community facilities programs. To meet this purpose, the Agency will make grants to public bodies and private nonprofit corporations, (such as States, counties, cities, townships, and incorporated towns and villages, boroughs, authorities, districts, and Indian tribes on Federal and State reservations) to provide assistance and/or training with respect to repairing essential community facilities. The Technical Assistance and/or training will assist communities, Indian tribes, and nonprofit corporations to identify and plan for community facility repairs as a result of damages resulting from Presidentially declared disasters in calendar year 2022, that exist in their area. Once those needs have been identified, the Grantee can assist in identifying public and private resources to finance those identified community facility needs.

This NOFA is being issued pursuant to the disaster funds made available by the Consolidated Appropriations Act, 2023. Grants will be provided to eligible applicants to provide technical assistance for repairing eligible essential community facilities damaged by Presidentially declared disasters in calendar year 2022. Subject to any updates to the Presidentially Declared Disasters, the following states have been identified with areas that have been impacted by qualifying events during CY 2022: Alaska, American Samoa, Arizona, California, Colorado, Florida, Idaho, Illinois,, Kansas, Kentucky, Maine, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, U.S. Virgin Islands, Vermont, Virginia, Washington, and West Virginia. For the most current list of Presidentially Declared Disasters, visit the United States (U.S.) Department of Homeland Security, Federal Emergency Management Agency (FEMA) website at *https://www.fema.gov/disaster/declarations.*

2. *Statutory and Regulatory Authority.* This NOFA is authorized pursuant to the CF TAT Grant program in title VI, section 6006 of the Agricultural Act of 2014 (Pub. L. 113–79) and Division N—Disaster Relief Supplemental Appropriations Act, 2023, of the Consolidated Appropriations Act, 2023, Public Law 117–328. Program regulations can be found at 7 CFR part 3570, subpart F.

3. *Definitions.* The definitions and abbreviations applicable to this Notice are published at 7 CFR 3570.252 (*https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XXXV/part-3570/subpart-F/section-3570.252*).

4. *Application of Awards.* The Agency will review, evaluate, and score applications received in response to this notice based on the provisions found in 7 CFR part 3570, subpart F, and as indicated in this notice.

The requirements for submitting an application can be found at 7 CFR 3570.267 (*https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XXXV/part-3570/subpart-F/section-3570.267*). All applicants can access application materials at *https://www.Grants.gov.* Applications must be received by the Agency by the due date listed in the **DATES** section of this Notice. Applications received after that due date will not be considered for funding. Paper copies of the applications must be submitted to the RDSO in which the applicant is headquartered. Electronic submissions must be submitted at *https://www.Grants.gov.* A listing of the RDSO contacts may be found at *https://www.rd.usda.gov/files/CF_State_Office_Contacts.pdf.* Applicants whose headquarters are in the District of Columbia will submit their application to the National Office in care of Shirley Stevenson, 1400 Independence Ave. SW, STOP 0787, Washington, DC 20250. Both paper and electronic applications must be received by the Agency by the deadlines stated in the **DATES** section of this Notice. The use of a courier and package tracking for paper applications is strongly encouraged. An applicant can only submit one application for funding. Application information for electronic submissions may be found at *https://www.Grants.gov.* Applications will not be accepted via FAX or email.

The Agency advises all interested parties that the applicant bears the burden in preparing and submitting an application in response to this notice whether or not the applicant receives any funding as a result of its application.

If the proposal involves large increases in employment; hazardous waste; a change in use, size, capacity, purpose, or location from an original facility; or is publicly controversial, the following is required: environmental documentation in accordance with 7 CFR part 1970; financial and statistical information; and written project description.

B. Federal Award Information

Type of Awards: Grants.

Fiscal Year Funds: FY 2023.

Available Funds: The FY 2023 funding amount is $2,500,000. Up to ten percent of the available funds may be awarded to the highest scoring Ultimate Recipient(s) as long as they score a minimum score of at least 70. The Agency reserves the right to reduce funding amounts based on the Agency's determination of available funding or other Agency funding priorities.

Award Amounts: Grant funds are limited and are awarded through a competitive process.

Minimum/Maximum Award Amount: Grant awards made to Ultimate Recipients will not exceed $50,000. The Agency has capped the grant awards for Technical Assistance Providers assisting Ultimate Recipients to not exceed $250,000. This applies even if the Technical Assistance Provider covers

entities in one county, multiple counties, or multiple states.

Anticipated Award Date: Awards will be made on or before March 15, 2024.

Performance Period: The grant period is to be for no more than three years.

Renewal or Supplemental Awards: At this time, the Agency does not anticipate supplemental funding for the program.

Type of Assistance Instrument: Grant agreement.

C. Eligibility Information

1. *Eligible Applicants and Project Purposes.* Both the applicant and the use of funds must meet eligibility requirements. The applicant eligibility requirements can be found at 7 CFR 3570.262. Eligible project purposes can be found at 7 CFR 3570.263. Ineligible project purposes can be found at 7 CFR 3570.264.

Non-tribal applicants proposing to provide Technical Assistance to Tribes should provide adequate documentation (for example, a letter of support from the Tribe or Tribes) that the Technical Assistance they are proposing to provide is supported by the Tribes they plan to serve.

Any corporation that has been convicted of a felony criminal violation under any Federal law within the past 24 months, or that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, is not eligible for financial assistance provided with full-year appropriated funds, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

Debarment and suspension information is required in accordance with 2 CFR parts 417 (Nonprocurement Debarment and Suspension) and 180 (OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement). The section heading ''What information must I provide before entering into a covered transaction with a Federal agency?'' located at 2 CFR 180.335 is part of OMB's Guidance for Grants and Agreements concerning Governmentwide Debarment and Suspension. Applicants are not eligible if they have been debarred or suspended or otherwise excluded from, or ineligible for, participation in Federal assistance programs under 2 CFR parts 180 and 417.

Technical Assistance Providers may be located anywhere within the United States. However, Technical Assistance Providers must provide technical assistance to Ultimate Recipients. The eligible Ultimate Recipient's project must be located in a rural area in a county with a disaster as declared by the President of the United States. The term rural or rural area is defined in section 343(a)(13)(C) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1991(a)(13)) as a city, town or, unincorporated area that has a population of not more than 20,000 inhabitants. The boundaries for unincorporated areas in determining populations will be based on the Census Designated Place (CDP.) Data from the most recent decennial census of the United States will be used in determining population.

2. *Eligible use of funds.* Grant funds must be used to provide technical assistance to repair essential community facilities damaged by Presidentially declared disasters in calendar year 2022. Examples of technical assistance may include identifying public and private funding resources, assisting communities in identifying and planning for repairs needed, and preparing applications for financial assistance. FEMA must have provided a notice declaring the disaster

3. *Cost Sharing or Matching.* Matching funds are not required. Matching funds must be in the form of cash. Up to 10 points may be awarded for applications that contain matching funds as provided in 7 CFR 3570.273(g).

4. *Other.* All submitted applications must meet the eligibility requirements in this notice and at 7 CFR part 3570 subpart F (*https://www.ecfr.gov/current/title-7/part-3570/subpart-F*), and application requirements noted in 7 CFR 3570.267 (*https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XXXV/part-3570/subpart-F/section-3570.267*.

Applications will not be considered for funding if they do not provide sufficient information to determine eligibility or are missing required elements.

D. Application and Submission Information

1. *Address to Request Application Package.* For further information on the CF TAT Grant Program, entities that want to apply for assistance should contact the USDA RDSO provided in the **ADDRESSES** section of this notice to obtain copies of the application package. Application information is also available at *https://www.grants.gov/.* If you require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720–2600 (voice and TDD) or the Federal Relay Service at (800) 877–8339. Prior to official submission of applications, applicants may request technical assistance or other application guidance from the Agency, as long as such requests are made prior to November 14, 2023. Technical assistance is not meant to be an analysis or assessment of the quality of the materials submitted, a substitute for agency review of completed applications, nor a determination of eligibility, if such determination requires in-depth analysis.

The Agency will not solicit or consider scoring nor eligibility information that is submitted after the application deadline. The Agency reserves the right to contact applicants to seek clarification information on materials contained in the submitted application.

2. *Content and Form of Application Submission.* An application must contain all of the required elements outlined in 7 CFR 3570.267. Each application must address the applicable scoring criteria presented in 7 CFR 3570.273 for the type of funding being requested. The applicant must provide documentation that the Ultimate Recipient is located within an eligible disaster area.

3. *System for Award Management and Unique Entity Identifier.* At the time of application, each applicant must have an active registration in the System for Award Management (SAM) before submitting its application in accordance with 2 CFR part 25. In order to register in SAM, entities will be required to request a Unique Entity Identifier (UEI). Instructions for obtaining the UEI are available at *https://sam.gov/content/entity-registration.*

a. Applicant must maintain an active SAM registration, with current, accurate and complete information, at all times during which it has an active Federal award or an application under consideration by a Federal awarding agency.

b. Applicant must ensure they complete the Financial Assistance General Certifications and Representations in SAM.

c. Applicants must provide a valid UEI in its application, unless determined exempt under 2 CFR 25.110.

d. The Agency will not make an award until the applicant has complied with all SAM requirements including providing the UEI. If an applicant has

not fully complied with the requirements by the time the Agency is ready to make an award, the Agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

4. *Submission Dates and Times.* Application Funding Submission Deadlines:

a. *Paper submissions:* The deadline for receipt of a paper application is 4:00 p.m. local time, November 29, 2023.

b. *Electronic submissions:* Electronic applications will be accepted via *Grants.gov.* The deadline for receipt of an electronic application via *Grants.gov* is 11:59 p.m. Eastern Time on November 24, 2023.

Explanation of Dates: The application dates and times are firm. If the due date falls on a Saturday, Sunday, or Federal holiday, the application is due the next business day. The Agency will not consider any application received after the deadline.

Note: Applicants intending to mail applications must provide sufficient time to permit delivery on or before the closing deadline date and time. Acceptance by the United States Postal Service or private mailer does not constitute delivery. Facsimile (FAX), electronic mail, and postage due applications will not be accepted. Prior to official submission of applications, applicants may request technical assistance or other application guidance from the Agency, as long as such requests are made prior to November 14, 2023.

5. *Intergovernmental Review.* This program is subject to Executive Order 12372, which requires intergovernmental consultation with state and local officials. RD conducts intergovernmental consultation as implemented with 2 CFR 415 subpart C. Not all States have chosen to participate in the intergovernmental review process. A list of participating States (SPOC List) is available at the following website: *https://www.whitehouse.gov/omb/management/office-federal-financial-management/.*

E. Application Review Information

1. *Criteria.* All eligible and complete applications will be evaluated and scored based on the selection criteria and weights contained in 7 CFR 3570.273 (*see, https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XXXV/part-3570/subpart-F/section-3570.273*). Failure to address any one of the criteria by the application deadline will result in the application being determined ineligible, and the application will not be considered for funding.

All applications that are complete and eligible will be scored and ranked competitively. The categories for scoring criteria used are the following:

The Agency will score each application using the following scoring factors unless otherwise provided in an annual Notice in the **Federal Register**:

(a) *Experience:* Applicant Experience at developing and implementing successful technical assistance and/or training programs:

(1) More than 10 years—40 points.

(2) More than 5 years to 10 years—25 points.

(3) 3 to 5 years—10 points.

(b) No prior grants received:

(1) Applicant has never received a CF TAT Grant—5 points.

(c) *Population:* The average population of proposed area(s) to be served:

(1) 2,500 or less—15 points.

(2) 2,501 to 5,000—10 points.

(3) 5,001 to 10,000—5 points.

(d) *MHI:* The average median household income (MHI) of proposed area to be served is below the higher of the poverty line or:

(1) 60 percent of the State's MHI—15 points.

(2) 70 percent of the State MHI—10 points.

(3) 90 percent of the State's MHI—5 points.

(e) *Multi-jurisdictional:* The proposed technical assistance or training project a part of a Multi-jurisdictional project comprised of:

(1) More than 10 jurisdictions—15 points.

(2) More than 5 to 10 jurisdictions—10 points.

(3) 3 to 5 jurisdictions—5 points.

(f) *Soundness of approach:* Up to 10 points.

(1) *Needs assessment:* The problem/issue being addressed is clearly defined, supported by data, and addresses the needs;

(2) Goals & objectives are clearly defined, tied to the need as defined in the work plan, and are measurable;

(3) Work plan clearly articulates a well thought out approach to accomplishing objectives & clearly identifies who will be served by the project;

(4) The proposed activities are needed in order for a complete Community Facilities loan and/or grant application.

(g) Matching funds:

(1) There is evidence of the commitment of other cash funds of 20% of the total project costs 10 points.

(2) There is evidence of the commitment of other cash funds of 10% of the total project costs 5 points.

(h) State Director discretionary points. The State Director may award up to 10 discretionary points for the highest priority project in each state, up to 7 points for the second highest priority project in each state and up to 5 points for the third highest priority project that address unforeseen exigencies or emergencies, such as the loss of a community facility due to an accident or natural disaster, or other areas of need in their particular state. The State Director will place written documentation in the project file each time the State Director assigns these points—Up to 10 points.

(i) Administrator discretionary points. The Administrator may award up to 20 discretionary points for projects to address geographic distribution of funds, emergency conditions caused by economic problems, natural disasters and other initiatives identified by the Secretary—Up to 20 points.

2. *Review and Selection Process.* The Rural Development State Offices will review applications to determine if applications are eligible for assistance based on requirements contained in 7 CFR 3570, subpart F. If determined eligible, your application will be submitted to the National Office. Funding of projects is subject to the intermediary's satisfactory submission of the additional items required by that subpart and the USDA RD Letter of Conditions. Discretionary priority points, under § 3570.273 (*see,* § 3570.273(h) and § 3570.273(i)), may be awarded with documented justification for the following categories:

- Assisting rural communities to recover economically through more and better market opportunities and through improved infrastructure.
- Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects.
- Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.

F. Federal Award Administration Information

1. *Federal Award Notices.* Successful applicants will receive notification for funding from the RDSO. Applicants must comply with all applicable statutes and regulations before the grant award can be approved. If an application is withdrawn by the applicant, it can be resubmitted and will be evaluated as a new application, provided the application is resubmitted before the submission deadline as stated in section D4 of this notice.

2. *Administrative and National Policy Requirements.* Additional requirements that apply to Grantees selected for this Program can be found in 7 CFR part

3570, subpart F (*https://www.ecfr.gov/current/title-7/part-3570/subpart-F*). Awards are subject to USDA grant regulations at 2 CFR part 400 (*https://www.ecfr.gov/current/title-2/part-400*) which incorporate the Office of Management and Budget (OMB) regulations at 2 CFR part 200 (*https://www.ecfr.gov/current/title-2/part-200*).

If the applicant wishes to consider beginning their project performance prior to the grant being officially closed, all pre-evaluation award costs must be approved in writing and in advance by the Agency.

In addition, all recipients of Federal financial assistance are required to report information about first-tier sub-awards and executive compensation (see, 2 CFR part 170 (*https://www.ecfr.gov/current/title-2/part-170*). The applicant will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282) and reporting requirements (see, 2 CFR 170.200(b) (*https://www.ecfr.gov/current/title-2/section-170.200#p-170.200(b)*), unless the recipient is exempt under 2 CFR 170.110(b) (*https://www.ecfr.gov/current/title-2/section-170.110#p-170.110(b)*).

The following additional requirements apply to Grantees selected for these Programs:

(a) Form RD 1940–1, ''Request for Obligation of Funds.''

(b) Form RD 1942–46, ''Letter of Intent to Meet Conditions.''

(c) Form SF–LLL, ''Disclosure of Lobbying Activities,'' if applicable.

(d) Form SF–270, ''Request for Advance or Reimbursement.''

(e) Form RD 400–4, ''Assurance Agreement'' must be completed by the applicant and each prospective ultimate recipient.

(f) Grantees must collect and maintain data provided by ultimate recipients on race, sex, and national origin and ensure ultimate recipients collect and maintain this data. Race and ethnicity data will be collected in accordance with OMB **Federal Register** notice, ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity'' (62 FR 58782), October 30, 1997. Sex data will be collected in accordance with title IX of the Education Amendments of 1972. These items should not be submitted with the application but should be available upon request by the Agency.

(e) The applicant and the ultimate recipient must comply with title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, Americans with Disabilities Act (ADA), section 504 of the Rehabilitation Act of 1973, Age Discrimination Act of 1975, Executive Order 12250, Executive Order 13166 Limited English Proficiency (LEP), and 7 CFR part 1901, subpart E.

3. *Reporting.* The Grantee must provide reports as required by 7 CFR part 3570, subpart F. A financial status report, SF 425 ''Federal Financial Report,'' and a project performance report will be required as provided in the grant agreement. The financial status report must show how grant funds and matching funds have been used to date. A final report may serve as the last report. Grantees shall constantly monitor performance to ensure that time schedules are being met and projected goals by time periods are being accomplished. Applicants may find the reporting requirements for this grant at 7 CFR 3570.276 (*https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XXXV/part-3570/subpart-F/section-3570.276*) in addition to any reports required by 2 CFR part 200 (*https://www.ecfr.gov/current/title-2/part-200*) and 2 CFR 400.1 (*https://www.ecfr.gov/current/title-2/section-400.1*) to 400.2 (*https://www.ecfr.gov/current/title-2/section-400.2*), and 2 CFR parts 415 to 422 (*https://www.ecfr.gov/current/title-2/section-415*).

G. Federal Awarding Agency Contact(s)

For general questions about this announcement, please contact your USDA RDSO as provided in the **ADDRESSES** section of this notice or the program website at: *https://www.rd.usda.gov/programs-services/community-facilities/community-facilities-direct-loan-grant-program.*

H. Other Information

(1) *Civil Rights Requirements.* All grants made under this Notice are subject to Title VI of the Civil Rights Act of 1964 as required by the USDA (7 CFR part 15, subpart A) and Section 504 of the Rehabilitation Act of 1973, Title VIII of the Civil Rights Act of 1968, Title IX, Executive Order 13166 (Limited English Proficiency), Executive Order 11246, and the Equal Credit Opportunity Act of 1974.

(2) *Paperwork Reduction Act.* In accordance with the Paperwork Reduction Act of 1995, the information collection requirement contained in this notice has been approved by OMB under OMB Control Number 0575–0198.

(3*) National Environmental Policy Act.* All recipients under this notice are subject to the requirements of 7 CFR 1970, available at: *https://rd.usda.gov/resources/environmental-studies/environmental-guidance.*

(4) *Nondiscrimination Statement.* In accordance with Federal civil rights laws and USDA civil rights regulations and policies, the USDA, its Mission Areas, agencies, staff offices, 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/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.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, staff office; or the Federal Relay Service at (800) 877–8339.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, USDA Program Discrimination Complaint Form, which can be obtained online at *https://www.usda.gov/sites/default/files/documents/ad-3027.pdf,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights about the nature and date of an alleged civil rights violation.

The completed AD–3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Joaquin Altoro,

Administrator, Rural Housing Service.

[FR Doc. 2023–18800 Filed 8–30–23; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–31–2023]

Foreign-Trade Zone (FTZ) 147; Authorization of Production Activity; PolyVisions Holdings, Inc.; (Plastic Resin Compounds); Manchester, Pennsylvania

On April 28, 2023, PolyVisions Holdings, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 147, in Manchester, Pennsylvania.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (88 FR 29080, May 5, 2023). On August 28, 2023, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: August 28, 2023.

Camille Evans,

Acting Executive Secretary.

[FR Doc. 2023–18816 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–878]

Stainless Steel Flanges From India: 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 stainless steel flanges (steel flanges) from India would be likely to lead to the continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Emily Halle, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0176.

SUPPLEMENTARY INFORMATION:

Background

On October 5, 2018, Commerce published in the **Federal Register** the order on steel flanges from India.[1] On May 1, 2023, Commerce published the notice of initiation of the first sunset review of the *Order,* in accordance with section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] In May 2023, Commerce received timely notices of intent to participate from Core Pipe Products, Inc. (Core Pipe) and Kerkau Manufacturing (Kerkau) (collectively, the domestic interested parties).[3] The domestic interested parties claimed interested party status under section 771(9)(C) of the Act as domestic producers engaged in the production of steel flanges in the United States.

On May 31, 2023, Commerce received timely and adequate substantive responses from the domestic interested parties.[4] We received no substantive responses from any other interested parties, including the Government of India, nor was a hearing requested. On June 20, 2023, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[5] 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.*

Scope of the Order

The merchandise covered by the *Order* is stainless steel flanges. For a complete description of the scope, *see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the accompanying Issues and Decision Memorandum. The issues discussed in the Issues and Decision Memorandum are the likelihood of continuation or recurrence of countervailable subsidies, the net countervailable subsidy rates that are likely to prevail, and the nature of the subsidies. 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). 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) and 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to the continuation or recurrence of countervailable subsidies at the rates listed below:

Producer/exporter	Subsidy rate (percent *ad valorem*)
Bebitz Flanges Works Private Limited	256.45
Echjay Forgings Private Limited	5.21
All Others	5.21

Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: August 24, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[1] *See Stainless Steel Flanges from India: Countervailing Duty Order,* 83 FR 50336 (October 5, 2018) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 26522 (May 1, 2023).

[3] *See* Core Pipe's Letter, ''Notice of Intent to Participate,'' dated May 15, 2023; and Kerkau's Letter, ''Notice of Intent to Participate by Kerkau Manufacturing,'' dated May 16, 2023.

[4] *See* Core Pipe's Letter, ''Domestic Interested Party's Substantive Response,'' dated May 31, 2023; and Kerkau's Letter, ''Substantive Response of Kerkau Manufacturing,'' dated May 31, 2023.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on May 1, 2023,'' dated June 20, 2023.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Countervailing Duty Order on Stainless Steel Flanges from India,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

1. Likelihood of Continuation or Recurrence of Countervailable Subsidies
2. Net Countervailable Subsidy Rates that Are Likely to Prevail
3. Nature of the Subsidies

VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2023–18811 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Civil Nuclear Trade Advisory Committee: Meeting of the Civil Nuclear Trade Advisory Committee

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice of federal advisory committee meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda for a meeting of the Civil Nuclear Trade Advisory Committee (CINTAC).

DATES: The meeting is scheduled for Thursday, September 14, 2023, from 9:00 a.m. to 4:00 p.m. Eastern Daylight Time (EDT). The deadline for members of the public to register, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EDT on Monday, September 11, 2023.

ADDRESSES: The meeting will be held in-person and online. Registered participants joining virtually will be emailed the login information for the meeting, which will be accessible as a livestream on Microsoft Teams. Registered participants joining in-person will be emailed instructions on accessing the designated meeting space. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted to Ms. Tshanda Kalombo, Office of Energy & Environmental Industries, International Trade Administration, (email: *tshanda.kalombo@trade.gov*). Members of the public should submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Ms. Tshanda Kalombo, Office of Energy & Environmental Industries, International Trade Administration, Room 28018, 1401 Constitution Ave. NW, Washington, DC 20230. (Phone: 202–482–2561; email: *tshanda.kalombo@trade.gov*).

SUPPLEMENTARY INFORMATION:

Background: The CINTAC was established under the discretionary authority of the Secretary of Commerce and in accordance with the Federal Advisory Committee Act (5 U.S.C. app.), in response to an identified need for consensus advice from U.S. industry to the U.S. Government regarding the development and administration of programs to expand U.S. exports of civil nuclear goods and services in accordance with applicable U.S. laws and regulations, including advice on how U.S. civil nuclear goods and services export policies, programs, and activities affect the U.S. civil nuclear industry's competitiveness and ability to participate in the international market.

Topics to be considered: The agenda for the Thursday, September 14, 2023, CINTAC meeting will include discussions of CINTAC priorities for its 2022–2024 charter term and activities related to the U.S. Department of Commerce's Civil Nuclear Trade Initiative.

Members of the public wishing to attend the meeting must notify Ms. Tshanda Kalombo at the contact information above by 5:00 p.m. EDT on Monday, September 11, 2023, in order to pre-register. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting.

A limited amount of time will be available for brief oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of 20 minutes. Individuals wishing to reserve speaking time during the meeting must contact Ms. Kalombo and submit a brief statement of the general nature of the comments and the name and address of the proposed participant by 5:00 p.m. EDT on Monday, September 11, 2023. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, ITA may conduct a lottery to determine the speakers.

Any member of the public may submit written comments concerning the CINTAC's affairs at any time before and after the meeting. Comments may be submitted to Ms. Tshanda Kalombo in the International Trade Administration's Office of Energy & Environmental Industries. For consideration during the meeting, and to ensure transmission to the Committee prior to the meeting, comments must be received no later than 5:00 p.m. EDT on Monday, September 11, 2023. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of CINTAC meeting minutes will be available within 90 days of the meeting.

Man K. Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2023–18864 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; CHIPS Environmental Questionnaire Information Collection

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 April 12, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Institute of Standards and Technology (NIST), Commerce.

Title: CHIPS Environmental Questionnaire Information Collection.

OMB Control Number: 0693–0093.

Form Number(s): None.

Type of Request: Regular.

Number of Respondents: 200.

Average Hours per Response: 8 hrs.

Burden Hours: 1,600 hrs.

Needs and Uses: The purpose of the Environmental Questionnaire is to ensure that the Department of Commerce is aware, in broad terms, of relevant environmental considerations, and can work with the potential applicant to ensure that the applicant can provide all required environmental information during the full application and due diligence stages when applying for funding. Each applicant must provide the requested information on the Environmental Questionnaire using the template which is available on the

CHIPS Incentives Program application portal.

Information to be collected includes information pertaining to an applicant's:

- Project Description
- Project Site/Affected Environment
- Resource Consumption Rates and Effluent Emissions Streams and Impacts
- Tribal, Historic, and Cultural Resources
- Project Setting
- Vegetation Resources
- Conservation Areas
- Coastal Zones and Navigable Waters
- Wetlands
- Floodplains
- Endangered Species
- Land Use and Zoning
- Solid Waste Management
- Hazardous or Toxic Substances
- Impacts to Water Quality/Water Resources
- Water Supply and Distribution System
- Wastewater Collection and Treatment Facilities
- Environmental Justice & Socioeconomics
- Transportation (Streets, Traffic and Parking)
- Air Quality
- Greenhouse Gases and their Environmental Effects
- Noise
- Health and Safety
- Permits and other Government Agency Involvement
- Public Notification/Controversy
- Environmental Experience and Approach

Affected Public: Business or other for-profit organizations.

Frequency: Once.

Respondent's Obligation: Mandatory to obtain or retain benefits.

Legal Authority: CHIPS Act of 2022 (Division A of Pub. L. 117–167) (the Act).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0693–0093.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2023–18809 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD298]

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of the Wreckfish Advisory Group and Wreckfish Sub-Committee. See **SUPPLEMENTARY INFORMATION** for agenda items.

DATES: The Wreckfish Advisory Group meeting will be held September 19, 2023, from 9 a.m. until 5 p.m. EDT. The Wreckfish Sub-Committee meeting will be held September 20, 2023, from 9 a.m. until 12:30 p.m. EDT.

ADDRESSES:

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

Meeting address: The meeting will be held at the Renaissance World Golf Village Resort, 500 South Legacy Trail, St. Augustine, FL 32092; phone: (904) 940–8000. The meeting will also be available via webinar. Registration is required. Webinar registration, an online public comment form, and briefing book materials will be available two weeks prior to the meeting at: *https://safmc.net/workgroups/.*

FOR FURTHER INFORMATION CONTACT: Christina Wiegand, Fishery Social Scientists, SAFMC; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *christina.wiegand@safmc.net.*

SUPPLEMENTARY INFORMATION: The Wreckfish Advisory Group will discuss Amendment 48 to the Fishery Management Plan for the Snapper Grouper Fishery of the South Atlantic (Amendment 48) addressing modernization of the wreckfish individual transferable quota (ITQ) program, and discuss other business as needed. The Wreckfish Sub-Committee will discuss Amendment 48 and input received from the Wreckfish Advisory Group. Current actions under consideration in Amendment 48 include: sector allocations, electronic reporting, fishing season, ITQ participation and eligibility requirements, fishery monitoring requirements, and cost recovery.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aid should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: August 28, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–18854 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD294]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Spiny Dogfish Advisory Panel will hold a public meeting. See **SUPPLEMENTARY INFORMATION** for agenda details.

DATES: The meeting will be held on Wednesday, September 20, 2023, from 5 p.m. until 7:30 p.m.

ADDRESSES: The meeting will be held via webinar. Connection information will be posted to the MAFMC's website calendar prior to the meeting at *www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is for the Advisory Panel to create a Fishery Performance Report that includes advisor input on recent spiny dogfish catch, specifications, and related management measures.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: August 28, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–18857 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; NMFS Observer Programs' Information That Can Be Gathered Only Through Questions

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 OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before October 30, 2023.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0593 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 Ken Keene, National Observer Program Coordinator, NOAA, 1315 East-West Highway, Silver Spring, MD 20910, (301–427–8158), and *kenneth.keene@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for revision and extension of an existing information collection.

The National Oceanic and Atmospheric Administration (NOAA), National Marine Fisheries Service (NMFS) deploys fishery observers on United States (U.S.) commercial fishing vessels and to fish processing plants in order to collect biological and economic data. NMFS has at least one observer program in each of its five Regions. These observer programs provide the most reliable and effective method for obtaining information that is critical for the conservation and management of living marine resources. Observer programs primarily obtain information through direct observations by employees or agents of NMFS; and such observations are not subject to the Paperwork Reduction Act (PRA). However, observer programs also collect the following information that requires clearance under the PRA: (1) Standardized questions of fishing vessel captains/crew or fish processing plant managers/staff, which include gear and performance questions, safety questions, and trip costs, crew size and other economic questions; (2) questions asked by observer program staff/contractors to plan observer deployments; (3) forms that are completed by observers and that fishing vessel captains are asked to review and sign; (4) questionnaires to evaluate observer performance; and (5) a form to certify that a fisherman is the permit holder when requesting observer data from the observer on the vessel.

The information collected will be used to: (1) Monitor catch and bycatch in federally managed commercial fisheries; (2) understand the population status and trends of fish stocks and protected species, as well as the interactions between them; (3) determine the quantity and distribution of net benefits derived from living marine resources; (4) predict the biological, ecological, and economic impacts of existing management action and proposed management options; and (5) ensure that the observer programs can safely and efficiently collect the information required for the previous four uses. In particular, these biological and economic data collection programs contribute to legally mandated analyses required under the Magnuson-Stevens Fishery Conservation and Management Act (MSA), the Endangered Species Act (ESA), the Marine Mammal Protection Act (MMPA), the National Environmental Policy Act (NEPA), the Regulatory Flexibility Act (RFA), Executive Order 12866 (E.O. 12866), as well as a variety of state statutes. The confidentiality of the data will be protected as required by the MSA, section 402(b).

This collection will be revised as follows. First is the expansion of observers to include an additional fishery. The Southeast region will begin sending observers out on Southeast reef fish fishery trips and thus needs to add this fishery to this collection. Second, NOAA is combining the Southeast observer efforts into one program. The third change is the West Coast Groundfish Observer Program (WCGOP) would like to start collecting the names of crew members within their observer logbooks. The data will be recorded on paper, scanned in, and stored according to vessel name. This information will only be accessed if there is an enforcement issue. The final change is also within the West Coast Groundfish Observer Program. They have introduced a new phone app that captains are using to declare upcoming fishing trips and NMFS is using to let them know if they have been selected for observer coverage. Other observer programs are also working on converting to smart phone apps, but they have not yet been implemented.

II. Method of Collection

The information will be collected by (1) NMFS observers while they are deployed on a vessel to observe a particular fishing trip; questions will be asked in-person to the captain, crew and/or owner (if on board the vessel) during the course of the observed trip; (2) via mail through follow up surveys of economic information not available during the trip; (3) via telephone or mail survey by the observer program staff or contractor planning to deploy observers; or (4) via feedback questionnaires mailed to the vessel owners or captains to evaluate observer performance.

III. Data

OMB Control Number: 0648–0593.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 13,212.

Estimated Time per Response: Northeast Fisheries Observer Program and At-Sea Monitors, 117 minutes; North Pacific Groundfish and Halibut Observer Program and Processing Plants, 56 minutes; Alaska Marine Mammal Observer Program, 15 minutes; West Coast Groundfish Observer Program, 31 minutes; Pacific Islands Region Observer Program, 86 minutes; Southeast Fishery Observer Program, 55 minutes; West Coast Region Observer Program, 62 minutes. Information will be collected for observed fishing trips and deployments to fish processing plants; therefore, there will be multiple responses for some respondents, but counted as one response per trip or plant visit.

Estimated Total Annual Burden Hours: 16,253.

Estimated Total Annual Cost to Public: $459,631.

Respondent's Obligation: Voluntary.

Legal Authority: The primary authority for NMFS to place observers on fishing vessels is included in the *Magnuson-Stevens Fishery Conservation and Management Act* (MSA), the *Endangered Species Act* (ESA), and the *Marine Mammal Protection Act* (MMPA).

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2023–18815 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD306]

September Management Track Peer Review Meeting

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

ACTION: Notice of public meeting.

SUMMARY: NMFS will convene the Assessment Oversight Panel (AOP) to convene the Management Track Assessment Peer Review Meeting for the purpose of reviewing Red Hake (North and South), Acadian Redfish, Skate Complex, Atlantic Mackerel, Northern Windowpane Flounder, and Spiny Dogfish stocks. The Management Track Assessment Peer Review is a formal scientific peer-review process for evaluating and presenting stock assessment results to managers for fish stocks in the offshore U.S. waters of the northwest Atlantic. Assessments are prepared by the lead stock assessment analyst and reviewed by an independent panel of stock assessment experts. The public is invited to attend the presentations and discussions between the review panel and the scientists who have participated in the stock assessment process.

DATES: The public portion of the Management Track Assessment Peer Review Meeting will be held from September 18, 2023 to September 20, 2023. The meeting will conclude on September 20, 2023 at 4:30 p.m. Eastern Standard Time. Please see **SUPPLEMENTARY INFORMATION** for the daily meeting agenda.

ADDRESSES: The meeting will be held via Google Meet:

https://meet.google.com/qza-zvku-oig

+1 252–987–4102

PIN: 732 891 507#

FOR FURTHER INFORMATION CONTACT: Alexander Dunn, 508–495–2195, *alexander.dunn@noaa.gov*.

SUPPLEMENTARY INFORMATION: For further information, please visit the Northeast Fisheries Science Center (NEFSC) website at *https://www.fisheries.noaa.gov/new-england-mid-atlantic/population-assessments/fishery-stock-assessments-new-england-and-mid-atlantic*. For additional information about management track assessment peer review, please visit the NEFSC web page at *https://www.fisheries.noaa.gov/new-england-mid-atlantic/population-assessments/management-track-stock-assessments*.

Daily Meeting Agenda—Management Track Peer Review Meeting

The agenda is subject to change; all times are approximate and may be changed at the discretion of the Peer Review Chair.

MONDAY, SEPTEMBER 18, 2023

Time	Subject	Presenter
9 a.m.–9:15 a.m	Welcome/Logistics/Conduct of Meeting	Michele Traver, Russ Brown, Adrian Jordaan, Chair.
9:15 a.m.–10:45 a.m	Red Hake (North and South)	Toni Chute.
	Discussion/Questions	Panel.
10:45 a.m.–11 a.m	Break.	
11 a.m.–12 p.m	Red Hake (North and South) cont	Toni Chute.
	Discussion/Questions	Panel.
12 p.m.–12:15 p.m	Morning Wrap Up Summary/Discussion	Panel.
12:15 p.m.–12:30 p.m	Public Comment	Public.
12:30 p.m.–1:30 p.m	Lunch.	
1:30 p.m.–3 p.m.	Acadian Redfish	Brian Linton.
	Discussion/Questions	Panel.
3 p.m.–3:15 p.m	Break.	
3:15 p.m.–4:30 p.m	Acadian Redfish cont	Brian Linton.

MONDAY, SEPTEMBER 18, 2023—Continued

Time	Subject	Presenter
	Discussion/Questions	Panel.
4:30 p.m.–4:45 p.m	Afternoon Wrap Up Summary/Discussion	Panel.
4:45 p.m.–5 p.m	Public Comment	Public.
5 p.m.	Adjourn.	

TUESDAY, SEPTEMBER 19, 2023

Time	Subject	Presenter
9 a.m.–9:05 a.m	Welcome/Logistics	Michele Traver, Adrian Jordaan, Chair.
9:05 a.m.–10:30 a.m	Skate Complex	Kathy Sosebee.
	Discussion/Questions	Panel.
10:30 a.m.–10:45 a.m	Break.	
10:45 a.m.–12 p.m	Skate Complex cont	Kathy Sosebee.
	Discussion/Questions	Panel.
12 p.m.–12:15 p.m	Morning Wrap Up Summary/Discussion	Panel.
12:15 p.m.–12:30 p.m	Public Comment	Public.
12:30 p.m.–1:30 p.m	Lunch.	
1:30 p.m.–3:30 p.m	Atlantic Mackerel	Kiersten Curti.
	Discussion/Questions	Panel.
3:30 p.m.–3:45 p.m	Break.	
3:45 p.m.–5 p.m	Northern Windowpane Flounder	Toni Chute.
	Discussion/Questions	Panel.
5 p.m.–5:15 p.m	Afternoon Wrap Up Summary/Discussion	Panel.
5:15 p.m.–5:30 p.m	Public Comment	Public.
5:30 p.m	Adjourn.	

WEDNESDAY, SEPTEMBER 20, 2023

Time	Subject	Presenter
9 a.m.–9:05 a.m	Welcome/Logistics	Michele Traver, Adrian Jordaan, Chair.
9:05 a.m.–12 p.m	Spiny Dogfish	Dvora Hart.
	Discussion/Questions	Panel.
12 p.m.–12:15 p.m	Morning Wrap Up Summary/Discussion	Panel.
12:15 p.m.–12:30 p.m	Public Comment	Public.
12:30 p.m.–1:30 p.m	Lunch.	
1:30 p.m.–4:30 p.m	Report Writing	Panel.
4:30 p.m	Adjourn.	

The meeting is open to the public; however, during the 'Report Writing' session on Friday, September 20th, the public should not engage in discussion with the Peer Review Panel.

Special Accommodations

This meeting is physically accessible to people with disabilities. Special requests should be directed to Alexander Dunn, via email *alexander.dunn@NOAA.gov.*

Dated: August 28, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023–18881 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD288]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Surfclam and Ocean Quahog Committee and Advisory Panel will hold a public webinar meeting. See **SUPPLEMENTARY INFORMATION** for agenda details.

DATES: The meeting will be held on Friday, September 15, 2023, from 9 a.m. until 12 p.m.

ADDRESSES: The meeting will be held via webinar. Connection information will be posted to the calendar prior to the meeting at *www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is for the Surfclam and Ocean Quahog Committee and Advisory Panel to receive updates on the Shellfish Biotoxin/Food and Drug Administration protocols that might impact the clam fisheries on Georges Bank, discuss the status of the Species Separation Requirements Amendment, and to develop recommendations for implementation

plan items for the Executive Committee to consider in October 2023.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: August 24, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–18775 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–C–2023–0006]

Future Strategies in Anticounterfeiting and Antipiracy

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Request for comments; extension of comment period.

SUMMARY: The United States Patent and Trademark Office (USPTO) published a request for comments in the **Federal Register** on May 25, 2023, seeking information from interested parties—in particular consumers, intellectual property rights holders, online marketplaces and platforms, physical marketplaces, parties who provide goods to the public, and other private sector stakeholders—on the evolution of counterfeiting and piracy in recent years and ways to identify and develop future anticounterfeiting and antipiracy strategies. Through this notice, the USPTO is extending the period for public comments until September 25, 2023.

DATES: Written comments must be received by 11:59 p.m. ET on September 25, 2023.

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

(1) *Electronic submissions:* Submit all electronic comments via the Federal eRulemaking Portal at *www.regulations.gov* (at the homepage, enter PTO–C–2023–0006 in the ''Search'' box, click the ''Comment'' icon, complete the required fields, and enter or attach your comments). The materials in the docket will not be edited to remove identifying or contact information, and the USPTO cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted only in Microsoft Word, Microsoft Excel, or Adobe PDF formats. Comments containing references to studies, research, and other empirical data that are not widely published should include copies of the referenced materials. Please do not submit additional materials. If you want to submit a comment with confidential business information that you do not wish to be made public, please submit the comment as a written/paper submission in the manner detailed below.

(2) *Written/paper submissions:* Send all written/paper submissions to: United States Patent and Trademark Office, Mail Stop OPIA, P.O. Box 1450, Alexandria, VA 22314. Submission packaging should clearly indicate that materials are responsive to Docket No. PTO–C–2023–0006, Office of Policy and International Affairs, Comment Request; Future Strategies in Anticounterfeiting and Antipiracy.

Submissions of confidential business information: Any submissions containing confidential business information must be delivered in a sealed envelope marked ''confidential treatment requested'' to the address listed above. Submitters should provide an index listing the document(s) or information they would like the USPTO to withhold. The index should include information such as numbers used to identify the relevant document(s) or information, the document title(s) and description(s), and relevant page numbers and/or section numbers within a document. Submitters should provide a statement explaining their grounds for objecting to the disclosure of the information to the public. The USPTO also requests that submitters of confidential business information include a non-confidential version (either redacted or summarized) of those confidential submissions that will be available for public viewing and posted on *www.regulations.gov.* In the event that the submitter cannot provide a non-confidential version of their submission, the USPTO requests that the submitter post a notice in the docket stating that they have provided the USPTO with confidential business information. Should a submitter fail to either docket a non-confidential version of their submission or post a notice that confidential business information has been provided, the USPTO will note the receipt of the submission on the docket with the submitter's organization or name (to the degree permitted by law) and the date of submission.

FOR FURTHER INFORMATION CONTACT: Ameen Imam, USPTO, Office of Policy and International Affairs, at 571–272–9300 or *ameen.imam@uspto.gov.* Please direct media inquiries to the USPTO's Office of the Chief Communications Officer at 571–272–8400.

SUPPLEMENTARY INFORMATION: On May 25, 2023, the USPTO published a **Federal Register** Notice requesting information from interested parties regarding their observations and insights into the future of anticounterfeiting and antipiracy strategies. In particular, as part of the USPTO's efforts to address counterfeiting and piracy, the notice requested information from consumers, intellectual property rights holders, online marketplaces and platforms, physical marketplaces, parties who provide goods to the public, and other private sector stakeholders on the evolution of counterfeiting and piracy in recent years and ways to identify and develop future anticounterfeiting and antipiracy strategies. *See* Future Strategies in Anticounterfeiting and Antipiracy, 88 FR 33872. The notice requested public comments on or before August 23, 2023.

Through this notice, the USPTO is extending the period for public comments until September 25, 2023, to give interested members of the public additional time to submit comments. All other information and instructions to commenters provided in the May 25, 2023, notice remain unchanged. Previously submitted comments do not need to be resubmitted. Any comments received after the previous deadline of August 23, 2023, and before the publication date of this notice will be treated as timely and given full consideration.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2023–18844 Filed 8–30–23; 8:45 am]

BILLING CODE 3510–16–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; VISTA Sponsor Survey

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the

Corporation for National and Community Service (operating as AmeriCorps) is proposing to revise an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by October 30, 2023.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) Electronically through *www.regulations.gov* (preferred method).

(2) *By mail sent to:* AmeriCorps, Attention: Robert Cox, 250 E Street SW, Washington, DC 20525.

(3) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (2) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

Comments submitted in response to this notice may be made available to the public through *regulations.gov.* For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Robert Cox, Director, Program Impact & Operations, AmeriCorps VISTA, (202) 420–1328, *rcox@cns.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: VISTA Sponsor Survey.

OMB Control Number: 3045–0191.

Type of Review: Revision.

Respondents/Affected Public: Businesses and organizations.

Total Estimated Number of Annual Responses: 800.

Total Estimated Number of Annual Burden Hours: 200.

Abstract: This information collection allows AmeriCorps to conduct surveys about Volunteers in Service to America (VISTA) project development, management, and sustainability, including member recruitment and retention. Surveys of project sponsors would be administered online, to help to identify implementation challenges and best practices among VISTA project sponsors. AmeriCorps will use the results to make program improvements and mitigate potential challenges, and to develop training and technical assistance materials to strengthen and enhance VISTA programming. Sponsors will be sent individualized emails and survey data will be merged with existing administrative data regarding project characteristics.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on *regulations.gov.*

Carly Bruder,

Acting Director, AmeriCorps VISTA.

[FR Doc. 2023–18812 Filed 8–30–23; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0077]

Privacy Act of 1974; System of Records

AGENCY: Department of Defense (DoD).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the DoD is modifying and reissuing a current Department-wide system of records titled, ''Defense Reasonable Accommodation and Assistive Technology Records,'' DoD–0007. This system of records was originally established to collect and maintain records concerning DoD civilian employees and other members of the public requesting or receiving disability-related accommodations. Additionally, this system was established to collect and maintain records concerning wounded, ill and injured Service members on Active Duty requesting or receiving assistive technology solutions. These accommodations, which relate to enabling civilian employees, members of the public, and certain Service members to access DoD employment, systems, facilities, and programs are hereafter referred to collectively as ''accessibility accommodations.'' This SORN is being updated to expand coverage to DoD civilian and military personnel, and applicants for DoD employment, who request an exemption from generally applicable policies for reasons relating to individual medical conditions, religious beliefs or practices, or matters of conscience. The DoD is also modifying various other sections within the SORN to improve clarity or update information that has changed.

DATES: This modified system of records is effective upon publication; however, comments on the new or modified Routine Uses will be accepted on or before October 2, 2023. The Routine Uses are effective at the close of the comment period.

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

* *Federal Rulemaking Portal: https://www.regulations.gov.*

Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are

received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Rahwa Keleta, Privacy and Civil Liberties Division, Directorate for Privacy, Civil Liberties and Freedom of Information, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Department of Defense, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700, *OSD.DPCLTD@mail.mil;* (703) 571–0070.

SUPPLEMENTARY INFORMATION:

Concurrently in today's issue of the **Federal Register**, DoD is publishing a technical amendment to correct an error in the Privacy Act exemption rule published for this system of records. The exemption rule at 32 CFR 310.13(e)(6) (July 22, 2021, 86 FR 38560) erroneously claims an exemption for this system of records from 5 U.S.C. 552a(c)(4), which generally requires the agency maintaining the system of records to inform recipients with whom it has shared a record if later the record was corrected or disputed pursuant to the requirements of 5 U.S.C. 552a(d). DoD's inclusion of subsection 552a(c)(4) was an error and DoD is removing it from the section of this notice entitled ''Exemptions Promulgated for this System'' and from the exemption rule.

I. Background

The DoD is updating the Defense Reasonable Accommodation and Assistive Technology Records SORN, DoD–0007, a DoD-wide Privacy Act system of records, to include records related to accessibility accommodations or exemptions from generally applicable policies for reasons relating to individual medical conditions, religious beliefs or practices, or matters of conscience. This SORN now expands coverage to civilian and military personnel, and applicants for DoD employment, who request an exemption from generally applicable policies for reasons relating to individual medical conditions, religious beliefs or practices, or matters of conscience.

Subject to public comment, the DoD proposes to add a new standard routine use I authorizing sharing in the context of Inspector General activities, and new routine use Q to allow for disclosure of religious information to authorized government officials for the purpose of making decisions and/or conducting an investigation into DoD's compliance with applicable laws, such as the Religious Freedom Restoration Act. The following sections of this SORN are also being modified: (1) the System Manager section to add an additional system manager; (2) the Authority for Maintenance of the System section to add additional authorities; (3) the Purpose of the System section to provide clarity on how the information will be used; (4) the Categories of Individuals Covered by the System section to expand the individuals covered; (5) the Categories of Records in the System section to clarify the different record types; (6) the Policies and Practices for Retention and Disposal of Records section to clarify the type of reasonable accommodation records; and (7) the Record Access Procedures section to clarify the DoD component's responsibilities under the Privacy Act.

DoD–0007 was originally established on July 22, 2021 (86 FR 38692) to support the receipt, review, and evaluation of requests made to DoD for reasonable accommodation(s), personal assistance services, or assistive technology solutions; the outcome of such requests; and the implementation of approved accommodations and personal assistance services. The original system of records was established to cover DoD civilian personnel and other individuals requesting or receiving reasonable accommodations or personal assistance services, and wounded, ill and injured Service members on Active Duty requesting or receiving assistive technology solutions.

II. Privacy Act

Under the Privacy Act, a ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined as a U.S. citizen or lawful permanent resident.

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A–108, the DoD has provided a report of this system of records to OMB and to Congress.

Dated: August 24, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Defense Reasonable Accommodations and Assistive Technology Records, DoD–0007.

SECURITY CLASSIFICATION:

Unclassified and Classified.

SYSTEM LOCATION:

Department of Defense (Department or DoD), located at 1000 Defense Pentagon, Washington, DC 20301–1000, and other Department installations, offices, or mission locations. Information may also be stored within a government-certified cloud, implemented and overseen by the Department's Chief Information Officer (CIO), 6000 Defense Pentagon, Washington, DC 20301–6000.

SYSTEM MANAGER(S):

The system managers are as follows:

A. Assistant Secretary of Defense for Manpower and Reserve Affairs, Office of the Under Secretary of Defense (Personnel & Readiness), 4000 Defense Pentagon, Washington, DC 20301–4000, *whsmc-alex.esd.mbx.osd-js-foia-requester-service-center@mail.mil.*

B. Deputy Director, Computer/Electronic Accommodations Program, Defense Human Resources Activity (DHRA), 4800 Mark Center Drive, Suite 05E22, Alexandria, VA 22350–4100, *cap@mail.mil.*

C. For the Department of the Army: Deputy Assistant Secretary of the Army, Command & Leadership Policy and Programs Division, Equity and Inclusion Agency, Department of the Army, 1000 Defense, Pentagon, Washington, DC 20301–1100, *usarmy.belvoir.hqda-oaa-ahs.mbx.rmda-foia-public-liaison@mail.mil.*

D. For the Department of the Air Force: Director, AF Equal Opportunity, Headquarters Air Force Manpower Personnel and Services, Department of the Air Force, 1000 Defense, Pentagon, Washington, DC 20301–1100, *usaf.pentagon.af-a1.mbx.a1q--workflow@mail.mil.*

E. For the Department of the Navy: Chief of Naval Personnel, Navy Inclusion and Diversity, Department of the Navy, 701 South Courthouse Road, (Bldg. 12, Rm. 4R140), Arlington, VA 22204, *DONFOIA-PA@navy.mil.*

F. For the U.S. Marine Corps: Marine Corps Community Services (MCCS) Human Resources Program Manager, Business and Support Services Division (MRG), Headquarters, United States Marine Corps, 3044 Catlin Avenue, Quantico, VA 22134–5003 or by phone at 703–432–0433/0431.

G. The Privacy Act responsibilities concerning access, amendment, and disclosure of the records within this system of records have been delegated to the DoD components. DoD components include the Military Departments of the Army, Air Force (including the U.S. Space Force), and Navy (including the U.S. Marine Corps), field operating agencies, major commands, field commands,

installations, and activities. To contact the system managers at the DoD component with oversight of the records, go to *www.FOIA.gov* to locate the contact information for each component's Freedom of Information Act (FOIA) office.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 113, Secretary of Defense; 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C. 1582, Assistive Technology, Assistive Technology Devices, and Assistive Technology Services; 10 U.S.C. 7013, Secretary of the Army; 10 U.S.C. 8013, Secretary of the Navy; 10 U.S.C. 9013, Secretary of the Air Force; 29 U.S.C. 791, Employment of Individuals with Disabilities; 29 U.S.C. 794, Nondiscrimination under Federal grants and programs; 29 U.S.C. 794d, Electronic and Information Technology; 42 U.S.C. Chapter 21B, Religious Freedom Restoration; 42 U.S.C. Chapter 21, Subchapter VI, Title VII of the Civil Rights Act; Executive Order 14035, Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce; Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government; E.O. 14043, Requiring Coronavirus Disease 2019 Vaccination for Federal Employees (revoked by E.O. 14099, Executive Order on Moving Beyond COVID-19 Vaccination Requirements for Federal Workers); 29 CFR 1605.2, Reasonable Accommodation without undue hardship as required by section 701(j) of title VII of the Civil Rights Act of 1964; 29 CFR 1614.203, Rehabilitation Act; DoD Directive 1020.1, Nondiscrimination on the Basis of Handicap in Programs and Activities Assisted or Conducted by the Department of Defense; DoD Instruction (DoDI) 6025.22, Assistive Technology (AT) for Wounded, Ill, and Injured Service Members; DoDI 1300.17, Religious Liberty In the Military Services; and DoDI 1304.28, The Appointment and Service of Chaplains.

PURPOSE(S) OF THE SYSTEM:

A. To support the receipt, review, and evaluation of requests made to DoD for reasonable accommodations which relate to enabling DoD civilian employees, members of the public, and wounded, ill and injured Service members on Active Duty to access DoD employment opportunities, information technology systems, facilities, and programs, hereafter referred to collectively as ''accessibility accommodations.''

B. To support the receipt, review, and evaluation of requests made to DoD for exemption from generally applicable policies for reasons relating to individual medical conditions, religious beliefs or practices, or matters of conscience, from DoD civilian and military personnel and applicants for DoD employment.

C. To support the operation of the DoD Computer/Electronic Accommodations Program (CAP) within DoD and at CAP-partnering organizations and Federal entities.

D. To support the tracking of the outcome of such requests, and the implementation of approved accommodations and exemptions. To track performance regarding the provision of accommodations by the Department and/or components.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

A. Individuals who are seeking ''accessibility accommodations,'' which relate to enabling civilian employees, members of the public, and wounded, ill, or injured Service members on Active Duty to access DoD employment, systems, facilities, and programs.

B. DoD military and civilian personnel, to include non-appropriated fund employees and the DoD personnel employed or assigned outside of the contiguous United States hires, also known as local national employees, and applicants for employment who are seeking an exemption from generally applicable policies for reasons relating to individual medical conditions, religious beliefs or practices, or matters of conscience.

C. Individuals participating in the DoD Computer/Electronic Accommodations Program (CAP) (including employees of CAP-partnering organizations and Federal entities).

D. Other individuals affiliated with the DoD who make accommodation requests covered by this system of records.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in this system include information regarding individuals requesting accessibility accommodations or exemptions (requesters) from generally applicable policies for reasons relating to individual medical conditions, religious beliefs or practices, or matters of conscience. Records include:

A. Personal and work-related information, such as name, DoD ID number, status (applicant or current employee), address(es), phone, email, official duty telephone number, occupational series, grade level, religious information, medical information, worker compensation claims number, date request was initiated, supervisor's name and phone number.

B. Requests for accommodation or exemption and the reason(s) the accommodation or exemption is requested, such as supporting documentation and related materials that substantiate the request, type(s) of accommodation or exemption requested, type(s) of accommodation or exemption provided, how the requested accommodation or exemption would assist or impact job performance, and the sources of technical assistance consulted in trying to identify a possible accommodation or exemption, documents detailing the final decision for the requested accommodation or exemption, appeals, claims, and complaints.

C. Information about religious belief, practice, or observance which serves as the basis for an accommodation or exemption request.

D. Specific information regarding the condition which serves as the basis for an accommodation or exemption request, including but not limited to the characteristics of impairment, job function difficulties, current limitation(s), past accommodation(s), specific accommodation(s), permanent or temporary nature of condition(s), major life activities impacted by the condition, and duration of condition.

E. Any other documentation, including religious or medical documentation, which serves as the basis for the accommodation or exemption request and the documents detailing the decision concerning the request, appeals, claims, and complaints.

F. Information about assistive devices and technology evaluated or selected; prior assistive solutions provided to the individual; vendor information; and acquisition or modification data.

G. Records associated with personal assistance services provided to individuals with targeted disabilities assistance.

RECORD SOURCE CATEGORIES:

Records and information stored in this system of records are obtained from individuals requesting accessibility accommodations and/or exemption from generally applicable policies for reasons relating to individual medical conditions, religious beliefs or practices, or matters of conscience. This may include the individual to whom the requested accommodation or exemption pertains, rehabilitation counselors, healthcare providers, and DoD

personnel who participate in the receipt, evaluation, review, decision, and implementation of reasonable accommodation requests, such as hiring officials, human resource officials, supervisors and managers, reasonable accommodation officials, review panels, attorneys, and deciding officials. It may also include organizations or Federal entities that participate in the DoD CAP.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Note: Medical information collected in support of the reasonable accommodation process is subject to confidentiality requirements. Medical information may be shared within the DoD only on an as-needed basis for purposes of resolving and implementing requests for reasonable accommodations and assistive technology solutions, in accordance with applicable law.

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, all or a portion of the records or information contained herein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal government when necessary to accomplish an agency function related to this system of records.

B. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

C. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

D. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

E. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

F. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

G. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the system of records; (2) the DoD determines as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

H. To another Federal agency or Federal entity, when the DoD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

I. To another Federal, State or local agency for the purpose of comparing to the agency's system of records or to non-Federal records, in coordination with an Office of Inspector General in conducting an audit, investigation, inspection evaluation, or other review as authorized by the Inspector General Act.

J. To such recipients and under such circumstances and procedures as are mandated by Federal statute, treaty.

K. To an authorized appeal grievance examiner, formal complaints examiner, administrative judge, equal employment opportunity investigator, arbitrator or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee.

L. Disclosure of medical condition or history information to authorized government officials for the purpose of conducting an investigation into DoD's compliance with the Rehabilitation Act.

M. Disclosure of medical condition or history information to first aid and safety personnel in the event an employee's medical condition might require emergency treatment or special procedures.

N. To Federal agencies/entities participating in the DoD CAP to permit the agency to carry out its responsibilities under the program.

O. To commercial vendors to permit the vendor to identify and provide assistive technology solutions for individuals with disabilities.

P. To any agency, organization, or person for the purposes of performing audit or oversight activities related to the operation of this system of records as authorized by law, but only information necessary and relevant to such audit or oversight function.

Q. Disclosure of religious information to authorized government officials for the purpose of making decisions and/or conducting an investigation into DoD's compliance with applicable laws, such as the Religious Freedom Restoration Act.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records may be stored electronically or on paper in secure facilities in a locked drawer behind a locked door. Electronic records may be stored locally on digital media; in agency-owned cloud environments; or in vendor Cloud Service Offerings certified under the Federal Risk and Authorization Management Program (FedRAMP).

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by requester name, DoD ID number, office/workstation address, bureau/office, assigned case tracking number, and disability accommodation request date.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

General Records Schedule 2.3 provides that reasonable accommodation case files are retained for at least three years after employee separation from the agency or all appeals are concluded, whichever is later. If an individual files a claim of disability or religious discrimination or another claim premised on the Constitution, federal statute, or other legal authority, or an action is brought by the Equal Employment Opportunity Commission or other relevant enforcement entity, all personnel records related to the claim will be retained until final disposition.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The DoD safeguards records in this system of records according to applicable rules, policies, and procedures, including all applicable

DoD automated systems security and access policies. DoD policies require the use of controls to minimize the risk of compromise of personally identifiable information (PII) in paper and electronic form and to enforce access by those with a need to know and with appropriate clearances. Additionally, the DoD has established security audit and accountability policies and procedures which support the safeguarding of PII and detection of potential PII incidents. The DoD routinely employs safeguards such as the following to information systems and paper recordkeeping systems: Multifactor log-in authentication including Common Access Card (CAC) authentication and password; physical token as required; physical and technological access controls governing access to data; network encryption to protect data transmitted over the network; disk encryption securing disks storing data; key management services to safeguard encryption keys; masking of sensitive data as practicable; mandatory information assurance and privacy training for individuals who will have access; identification, marking, and safeguarding of PII; physical access safeguards including multifactor identification physical access controls, detection and electronic alert systems for access to servers and other network infrastructure; and electronic intrusion detection systems in DoD facilities.

Custodians of medical records in this system of records must have the ability to protect this information from being accessed or accessible by others without a need to know. This may involve providing custodians with access to dedicated machines for copying, printing, or faxing; dedicated, secure file storage; and temporary or permanent workspaces where telephone conversations cannot be overheard by those without a need to know.

RECORD ACCESS PROCEDURES:

Individuals seeking access to their records should follow the procedures in 32 CFR part 310. Individuals should address written inquiries to the DoD component or office with oversight of the records, as it has Privacy Act responsibilities concerning access, amendment, and disclosure of the records within this system of records. The public may identify the contact information for the appropriate DoD office through the following website: www.FOIA.gov. Signed written requests should contain the name and number of this system of records notice along with the full name, current address, and email address. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the appropriate format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

CONTESTING RECORD PROCEDURES:

Individuals seeking to amend or correct the content of records about them should follow the procedures in 32 CFR part 310.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system of records should follow the instructions for Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

The DoD has exempted records maintained in this system from 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(4)(G), (H), and (I); and (f) pursuant to 5 U.S.C. 552a(k)(1). In addition, when exempt records received from other systems of records become part of this system, DoD also claims the same exemptions for those records that are claimed for the prior system(s) of records of which they were a part, and claims any additional exemptions set forth here. An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c), and (e), and published in 32 CFR part 310.

HISTORY:

July 22, 2021, 86 FR 38692.

[FR Doc. 2023–18687 Filed 8–30–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–HA–0080]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 30, 2023.

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

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Health Agency, J–5 Strategy, Plans, and Functional Integration Analytics and Evaluation Division Defense Health Headquarters, ATTN: Wanda Oka, 7700 Arlington Boulevard, Office 1M225, Falls Church, VA 22041 or call (703) 681–1697.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Personnel Accountability and Assessment for a Public Health Emergency; DD Form 3112; OMB Control Number 0720–0067.

Needs and Uses: The principal purpose of the DD Form 3112, ''Personnel Accountability and

Assessment Notification for a Public Health Emergency,'' is to collect information used to protect the health and safety of individuals working in, residing on, or assigned to DoD installations, facilities, field operations, and commands, and to protect the DoD mission. When authorized by DoD, this form may be used to provide information about individuals who are infected or otherwise impacted by a public health emergency or similar occurrence or when there is an isolated incident in which an individual learns they have been exposed to a contagious disease or hazardous substance/agent. The form will also be used to document personnel accountability for and status of DoD-affiliated personnel in a natural or man-made disaster, or when directed by the Secretary of Defense. Such events could include severe weather events, acts of terrorism or severe destruction. The collection of this information is necessary to support the DoD in protecting the health and safety of DoD-affiliated individuals and maintain the DoD mission.

The information collected via the DD–3112 will inform decisions made about the status of DoD facilities and spaces that Affected Individuals have entered. This information may be used to make decisions to protect the health and safety of DoD personnel and facilities. It may also be used to notify other individuals who may have contacted the Affected Individual.be used to make informed decisions about the status of the DoD facility and office space that subject individuals exposed to communicable diseases or hazardous substances/agents have entered. This information may be used to make Health Protection Condition (HPCON) level decisions. It may also be used to notify other individuals who may have been in contact with the subject individual(s).

Affected Public: Individuals and households.

Annual Burden Hours: 8,333.3 Hours.

Number of Respondents: 100,000.

Responses per Respondent: 1.

Annual Responses: 100,000.

Average Burden per Response: 5 Minutes.

Frequency: On occasion.

Dated: August 28, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18847 Filed 8–30–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0032]

Submission for OMB Review; Comment Request; Correction

AGENCY: Defense Counterintelligence and Security Agency (DCSA), Department of Defense (DoD).

ACTION: 30-Day information collection notice; correction.

SUMMARY: On August 21, 2023, the DoD published a notice with an incorrect docket identifier. This correction informs the public of the correct docket identifier.

DATES: This correction is effective August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Patricia Toppings, 571–372–0485.

SUPPLEMENTARY INFORMATION: The DoD published a notice on August 21, 2023 (88 FR 56806). Subsequent to publication of the notice, DoD realized that the docket identifier was incorrect. The docket identifier published as ''DoD–2023–08083.'' The docket identifier is corrected to read as set forth above.

Dated: August 28, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18856 Filed 8–30–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0079]

Proposed Collection; Comment Request

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

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 30, 2023.

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

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Office of the Under Secretary of Defense for Personnel and Readiness, 1500 Defense Pentagon, Washington, DC 20301–4000, Ronald Garner, 703–693–1059.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for Annuity Certain Military Surviving Spouses; DD Form 2769; OMB Control Number 0704–0402.

Needs and Uses: The Defense Authorization Act of Fiscal Year 1998, Public Law 105–85, Section 644, requires the Secretary of Defense to pay an annuity to qualified surviving spouses. The DD Form 2769, ''Application for Annuity-Certain Military Surviving Spouses,'' used in this information collection, provides a vehicle for the surviving spouse to apply for the annuity benefit. The Department will use this information to determine if the applicant is eligible for the annuity benefit and make payment to the surviving spouse. The respondents of this information collection are surviving spouses of each

member of the uniformed services who (1) died before March 21, 1974, and was entitled to retired or retainer pay on the date of death or (2) was a member of a reserve component of the Armed Forces during the period beginning on September 21, 1972, and ending on October 1, 1978, and at the time of member's death would have been entitled to retired pay

Affected Public: Individuals or households.

Annual Burden Hours: 100.

Number of Respondents: 400.

Responses per Respondent: 1.

Annual Responses: 400.

Average Burden per Response: 15 minutes.

Frequency: As required.

Dated: August 28, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18846 Filed 8–30–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0155]

Agency Information Collection Activities; Comment Request; REL Peer Review: Pilot Data Collection Methods for Examining the Use of Research Evidence

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before October 30, 2023.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2023–SCC–0155. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, the Department will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 4C210, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Christopher Boccanfuso, 202–245–6832.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: REL Peer Review: Pilot Data Collection Methods for Examining the Use of Research Evidence.

OMB Control Number: 1850–NEW.

Type of Review: A new ICR.

Respondents/Affected Public: Individuals and households.

Total Estimated Number of Annual Responses: 115.

Total Estimated Number of Annual Burden Hours: 43.

Abstract: The Institute of Education Sciences (IES) within the U.S. Department of Education (ED) requests clearance for data collection activities to support a pilot study of the reliability and validity of survey items used to assess the use of research evidence (URE) among education agencies and other partners served by the Regional Educational Laboratories (RELs). The REL program is an essential IES investment focused on partnering with State and local education agencies use evidence to improve education outcomes by creating tangible research products and providing engaging learning experiences and consultation. IES seeks to better understand how REL partners use research evidence to improve education outcomes and the role of RELs in promoting URE among partners. This study will test the reliability and validity of new and extant URE items in the REL context. Specifically, the study will (1) assess how existing items from the URE literature perform in a REL context and (2) assess the reliability and validity of a small set of items from the Stakeholder Feedback Surveys (SFS) that are currently administered to REL partners and used by IES to improve the work of REL contractors, inform the REL program as a whole, and address internal requests such as the Congressional Budget Justification. The reliability and validity of the new and existing survey items will be assessed through two data collection activities: an online survey administered to a set of partnerships across RELs and follow-up interviews with a subset of REL partners.

Dated: August 28, 2023.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–18875 Filed 8–30–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice Inviting Publishers To Submit Tests for a Determination of Suitability for Use in the National Reporting System for Adult Education

AGENCY: Office of Career, Technical, and Adult Education, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary of Education invites publishers to submit tests for review and approval for use in the National Reporting System for Adult Education (NRS) and announces the date by which publishers must submit these tests. This notice relates to the

approved information collection under OMB control number 1830–0567.

DATES: *Deadline for transmittal of applications:* October 1, 2023.

ADDRESSES: Submit your application by email to *NRS@air.org.*

FOR FURTHER INFORMATION CONTACT: John LeMaster, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–7240. Telephone: (202) 245–6218. Email: *John.LeMaster@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: The Department's regulations for Measuring Educational Gain in the National Reporting System for Adult Education, 34 CFR part 462 (NRS regulations), include procedures for determining the suitability of tests for use in the NRS.

As provided in the NRS regulations, the Secretary only reviews tests submitted by a test publisher, and any such tests must be submitted by the beginning of the review cycle on October 1, 2023. 34 CFR 462.10. Only tests submitted by the due date will be reviewed in this review cycle. Any tests submitted after October 1, 2023, will not be reviewed until the review cycle that begins on October 1, 2024.

Review Criteria: To be suitable for use in the NRS, a test must meet the criteria and requirements established in 34 CFR 462.13.

Submission Requirements:

(a) All test applications must comply with the requirements in 34 CFR 462.11.

(b) In accordance with 34 CFR 462.10, the deadline for transmittal of applications in this fiscal year is October 1, 2023.

(c) Applications are due by 11:59 p.m. local time on October 1, 2023. Retain a copy of your sent email message and all email attachments as proof that you timely submitted your application.

(d) Applications submitted after the application deadline date will not be considered in the October 1, 2023, review cycle. Any such applications will be considered timely for the October 1, 2024, deadline date and review cycle.

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 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.

Authority: 29 U.S.C. 3292.

Amy Loyd,

Assistant Secretary for Career, Technical, and Adult Education.

[FR Doc. 2023–18797 Filed 8–30–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2701–000]

MRP Rocky Road LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of MRP Rocky Road LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 14, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (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: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18851 Filed 8–30–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15055–001]

Northern States Power Company; Notice of Application Tendered for Filing With the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original Major License.

b. Project No.: 15055–001.

c. *Date Filed:* August 18, 2023.

d. *Applicant:* Northern States Power Company, a Wisconsin Corporation (NSP).

e. *Name of Project:* Gile Flowage Storage Reservoir Project (project).

f. *Location:* On the West Fork of the Montreal River in Iron County, Wisconsin approximately 3 miles southwest of the towns of Hurley, Wisconsin and Ironwood, Michigan.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Matthew Miller, Hydro License Compliance Consultant, Xcel Energy, 1414 West Hamilton Avenue, P.O. Box 8, Eau Claire, Wisconsin 54702–0008; telephone at (715) 737–1353, or email at *matthew.j.miller@xcelenergy.com.*

i. *FERC Contact:* Nicholas Ettema, telephone at (312) 596–4447, or email at *nicholas.ettema@ferc.gov.*

j. This application is not ready for environmental analysis at this time.

k. *Project Description:* The project includes the following existing facilities: (1) a 902.6-foot-long, 32.5-foot-high dam that includes: (a) a 300-foot-long west earthen embankment with a crest elevation of 1495.0 feet National Geodetic Vertical Datum of 1929 (NGVD 29); (b) a 27.6-foot-long concrete section that includes a 6-foot-wide, 6-foot-high sluice gate with a trashrack with 2.625-inch clear bar spacing, and a 16-foot-wide, 12-foot-high Tainter gate; and (c) a 575-foot-long east earthen embankment with a crest elevation of 1495.0 feet NGVD 29; (2) an impoundment with a surface area of 3,454 acres at an elevation of 1,490 feet NGVD 29 and usable storage capacity of 32,713 acre-feet between surface elevations of 1,475 feet and 1,490 feet NGVD 29; (3) a 35-foot-long concrete conduit downstream of the sluice gate; (4) an approximately 60-foot-long concrete apron downstream of the dam; (5) a 27.5-foot-wide, 11.8-foot-long brick gatehouse integral to the concrete section of the dam; and (6) appurtenant facilities. The project does not contain any generating facilities.

The project includes the following existing recreation facilities: (1) a canoe take-out site on the shoreline of the impoundment, at the east earthen embankment; (2) an approximately 100-foot-long canoe portage route; and (3) a canoe put-in site located on the east shore of the West Fork of the Montreal River, immediately downstream of the project dam.

An August 19, 2020 order, issued in FERC Docket No. UL20–1–000, found that the project is required to be licensed because it is part of a complete unit of development that includes the Saxon Falls Hydroelectric Project No. 2610 (Saxon Project) and the Superior Falls Hydroelectric Project No. 2587 (Superior Project).[1] NSP currently operates the project to augment flow in the West Fork of the Montreal River during the summer and winter low-flow periods for hydroelectric generation at the downstream Saxon and Superior Projects. NSP maintains the impoundment levels between 1,475 feet and 1,490 feet NGVD 29. To protect aquatic resources, NSP releases a continuous minimum flow of 10 cubic feet per second or inflow, whichever is less, downstream of the project dam. NSP provides the minimum flow through the sluice gate.

To augment flows available for generation at the Saxon Falls Project and Superior Falls Project, NSP typically begins drawing down the impoundment in the summer and winter, respectively around May 1 and December 1. The project has a maximum drawdown of 15 feet, but the average summer and winter drawdowns are typically 5.2 feet and 6.8 feet, respectively. The impoundment remains at the lower level until seasonal inflow refills the impoundment in the fall and spring. To protect aquatic and recreation resources, under normal project operation, NSP limits the rate of the impoundment drawdowns to 0.2 feet per day.

[1] *See Northern States Power Company—Wisconsin,* 172 FERC ¶ 62,093 (2020).

NSP is not proposing any new facilities or operational changes that would alter the current project operation. The proposed project boundary encompasses approximately 3,457.5 acres, including: (1) the impoundment; (2) 2.1 acres of land associated with the project facilities listed above; (3) 0.2 acre of water associated with the West Fork of the Montreal River immediately downstream of the project dam; (4) 0.3 acre of land north of the west earthen embankment; and (5) 0.9 acre of land north of the east earthen embankment.

l. In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (*e.g.,* license application) via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document (P–15055). For assistance, contact FERC at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). At this time, the Commission has suspended access to the Commission's Public Reference Room.

m. You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. 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.*

o. Procedural Schedule: The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Issue Deficiency Letter	September 2023.
Request Additional Information (if necessary)	September 2023.
Notice of Acceptance/Notice of Ready for Environmental Analysis	March 2024.
Filing of recommendations, preliminary terms and conditions, and preliminary fishway prescriptions	May 2024.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18871 Filed 8–30–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Pre-Recorded Workshop: ''Fundamentals of Intervention in FERC Matters''; Office of Public Participation Fundamentals for Participating in FERC Matters

Office of Public Participation (OPP) staff will release an educational video on October 25, 2023, in the above-referenced proceedings. The video, titled ''FERC Intervention: Powering Up Your Participation'' will explain how and why a member of the public may choose to intervene in a Federal Energy Regulatory Commission (FERC) proceeding. Staff will address common questions about filing an intervention at FERC.

The conversation will cover intervening in energy infrastructure projects (natural gas pipelines, liquefied natural gas (LNG) terminals, or hydroelectric dams) proceedings, and in electric rates proceedings. OPP directly helps constituents to navigate FERC proceedings by explaining what an intervention is and how to intervene in the correct docket. Intervention is the procedural pathway to becoming a party in a proceeding at FERC.

Further questions which will be addressed include: What does it mean to file an intervention in a docket? Is that the same as filing a comment? Does that make me a party to a case, and what does becoming a party to a case mean? Is a lawyer required? Are there examples or templates? What should I know before deciding to intervene?

OPP wants to hear from you. What questions do you have? What has been your experience intervening, commenting, or otherwise navigating a FERC proceeding?

The video will be posted on FERC's YouTube channel on Office of Public Participation's playlist. It will include captioning in English and Spanish and will be compliant with section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–502–8659 (TTY) or send a FAX to 202–208–2106 with the required accommodations.

Please file your questions or comments in the docket on or before Wednesday September 20, 2023. If you need help with filing or have any other questions, feel free to reach out to Matthew Rolnick of the Commission's Office of Public Participation at *Matthew.Rolnick@ferc.gov* or *OPP@ferc.gov.*

Dated: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18863 Filed 8–30–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2694–000]

Cereal City Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Cereal City Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 14, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (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: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18868 Filed 8–30–23; 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 and Oil Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR23–64–000.

Applicants: Rocky Mountain Natural Gas LLC.

Description: § 284.123 Rate Filing: RMNG SOC Filing to be effective 8/13/2023.

Filed Date: 8/24/23.

Accession Number: 20230824–5056.

Comment Date: 5 p.m. ET 9/14/23.

Docket Numbers: RP23–466–000.

Applicants: Florida Gas Transmission Company, LLC.

Description: Motion Filing: Motion Tariff Records into Effect RP23–466–000 to be effective 8/27/2023.

Filed Date: 8/25/23.

Accession Number: 20230825–5057.

Comment Date: 5 p.m. ET 9/6/23.

Docket Numbers: RP23–978–000.

Applicants: EQT Energy, LLC, THQ Marketing, LLC.

Description: Joint Petition for Temporary Waivers of Capacity Release Regulations, et al. of EQT Energy, LLC, et al.

Filed Date: 8/24/23.

Accession Number: 20230824–5121.

Comment Date: 5 p.m. ET 9/8/23.

Docket Numbers: RP23–979–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: Compliance filing: Cancel TETCO X Rate Sch Comp Filing to be effective 9/1/2023.

Filed Date: 8/25/23.

Accession Number: 20230825–5045.

Comment Date: 5 p.m. ET 9/6/23.

Docket Numbers: RP23–980–000.

Applicants: Texas Eastern Transmission, LP.

Description: Compliance filing: TETLP August 2023 Penalty Disbursement Report to be effective N/A.

Filed Date: 8/25/23.

Accession Number: 20230825–5070.

Comment Date: 5 p.m. ET 9/6/23.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP20–1060–010.

Applicants: Columbia Gas Transmission, LLC.

Description: Compliance filing: LPS Plan to be effective N/A.

Filed Date: 8/25/23.

Accession Number: 20230825–5124.

Comment Date: 5 p.m. ET 9/6/23.

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

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

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

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Dated: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18865 Filed 8–30–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2699–000]

MRP Elgin LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of MRP Elgin LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 14, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

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Dated: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18862 Filed 8–30–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15055–001]

Northern States Power Company; Notice of Environmental Site Review

On September 27, 2023, at 3:00 p.m. (Central Daylight Time), Commission staff and Northern States Power Company (Northern States Power), the applicant for the Gile Flowage Storage Reservoir Project No. 15055 (project), will conduct an environmental site review of the project. All interested individuals, agencies, Indian Tribes, non-governmental organizations, and other stakeholders are invited to attend.

The site review will include the project dam, spillway, impoundment, and recreational facilities associated with the project, and will commence at the adjacent Gile Park. Please note that all participants are responsible for their own transportation to/from the project and during the site review tour. If you are interested in attending, or have questions regarding the site review, please contact Matthew Miller of Northern States Power via email at *matthew.j.miller@xcelenergy.com,* or telephone at (715) 737–1353 on or before Friday, September 22, 2023.

Participants will meet at Gile Park located at 14 Park Street, Gile, Wisconsin 54525. Participants should arrive early for coordination purposes and to begin the tour promptly at 3:00 p.m. Additionally, participants must wear sturdy, closed-toe shoes, or boots.

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: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18870 Filed 8–30–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–29–000]

Saguaro Connector Pipeline, LLC; Notice of Availability of the Environmental Assessment for the Proposed Saguaro Connector Pipeline Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Saguaro Connector Pipeline Project (Project), proposed by Saguaro Connector Pipeline, LLC (Saguaro) in the above referenced docket. Saguaro requests authorization from the Commission to construct, install, operate, and maintain an approximate 1,000-foot, 48-inch-diameter natural gas pipeline in Hudspeth County, Texas. The proposed Project would cross the United States and Mexico International Boundary below the Rio Grande. According to Saguaro, the Project would serve as an interconnection to transport natural gas produced in Texas to a pipeline in Chihuahua, Mexico. The 48-inch-diameter natural gas pipeline is designed for a capacity of 2.834 billion standard cubic feet per day. The Project would not have permanent aboveground facilities.

The EA assesses the potential environmental effects of the construction and operation of the Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The Project includes the following components:

- approximately 1,000 feet of 48-inch-diameter natural gas pipeline;
- approximately 1,000 feet of 50-foot-wide permanent right-of-way;
- additional temporary workspaces (total of 14.2 acres); and
- 6.9 miles of temporary access road (Indian Hot Springs Road).

The Commission mailed a copy of the *Notice of Availability* of the EA to Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the project area. The EA is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the natural gas environmental documents page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). In addition, the EA may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://elibrary.ferc.gov/eLibrary/search*) select ''General Search'' and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.,* CP23–29). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

The EA is not a decision document. It presents Commission staff's independent analysis of the environmental issues for the Commission to consider when addressing the merits of all issues in this proceeding. Any person wishing to comment on the EA may do so. Your comments should focus on the EA's disclosure and discussion of potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to

making its decision on this Project, it is important that we receive your comments in Washington, DC on or before 5:00 p.m. Eastern Time on September 25, 2023.

For your convenience, there are three methods you can use to file your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions, so that your comments are properly recorded.

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

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

(1) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP23–29–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered. Only intervenors have the right to seek rehearing or judicial review of the Commission's decision. At this point in this proceeding, the timeframe for filing timely intervention requests has expired. Any person seeking to become a party to the proceeding must file a motion to intervene out-of-time pursuant to Rule 214(b)(3) and (d) of the Commission's Rules of Practice and Procedures (18 CFR 385.214(b)(3) and (d)) and show good cause why the time limitation should be waived. Motions to intervene are more fully described at *https://www.ferc.gov/how-intervene.*

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

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.*

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

Dated: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18869 Filed 8–30–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG23–263–000.

Applicants: Parliament Solar LLC.

Description: Parliament Solar LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.

Filed Date: 8/24/23.

Accession Number: 20230824–5177.

Comment Date: 5 p.m. ET 9/14/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER21–829–001.

Applicants: Weaver Wind, LLC.

Description: Compliance filing: Notice of Change in Status to be effective 8/25/2023.

Filed Date: 8/24/23.

Accession Number: 20230824–5163.

Comment Date: 5 p.m. ET 9/14/23.

Docket Numbers: ER21–830–001.

Applicants: Weaver Wind Maine Master Tenant, LLC.

Description: Compliance filing: Notice of Change in Status to be effective 8/25/2023.

Filed Date: 8/24/23.

Accession Number: 20230824–5165.

Comment Date: 5 p.m. ET 9/14/23.

Docket Numbers: ER23–2147–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 1885R13 Evergy Kansas Central, Inc. NITSA NOA—Bronson to be effective 9/1/2023.

Filed Date: 8/25/23.

Accession Number: 20230825–5140.

Comment Date: 5 p.m. ET 9/15/23.

Docket Numbers: ER23–2224–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 1976R13 FreeState Electric Cooperative, Inc. NITSA and NOA to be effective 9/1/2023.

Filed Date: 8/25/23.

Accession Number: 20230825–5104.

Comment Date: 5 p.m. ET 9/15/23.

Docket Numbers: ER23–2255–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 3599R2 Missouri Electric Commission NITSA NOA to be effective 9/1/2023.

Filed Date: 8/25/23.

Accession Number: 20230825–5173.

Comment Date: 5 p.m. ET 9/15/23.

Docket Numbers: ER23–2278–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 1276R31 Evergy Metro NITSA NOA to be effective 9/1/2023.

Filed Date: 8/25/23.

Accession Number: 20230825–5153.

Comment Date: 5 p.m. ET 9/15/23.

Docket Numbers: ER23–2428–002.

Applicants: Bucksport Generation LLC.

Description: Tariff Amendment: Bucksport Generation LLC, IROL–CIP Rate Schedule Further Amendment to be effective 9/29/2023.

Filed Date: 8/24/23.

Accession Number: 20230824–5171.

Comment Date: 5 p.m. ET 9/14/23.

Docket Numbers: ER23–2703–000.

Applicants: MRP Elgin LLC.

Description: Initial rate filing: MRP Elgin LLC Initial Reactive Rate Schedule to be effective 8/25/2023.

Filed Date: 8/25/23.
Accession Number: 20230825–5047.
Comment Date: 5 p.m. ET 9/15/23.
Docket Numbers: ER23–2704–000.
Applicants: MRP Rocky Road LLC.
Description: Initial rate filing: MRP Rocky Road LLC Initial Reactive Rate Schedule to be effective 8/25/2023.
Filed Date: 8/25/23.
Accession Number: 20230825–5048.
Comment Date: 5 p.m. ET 9/15/23.
Docket Numbers: ER23–2705–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: § 205(d) Rate Filing: Initial Filing of Rate Schedule FERC No. 358 to be effective 7/26/2023.
Filed Date: 8/25/23.
Accession Number: 20230825–5075.
Comment Date: 5 p.m. ET 9/15/23.
Docket Numbers: ER23–2706–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: § 205(d) Rate Filing: Amendment to Rate Schedule FERC No. 39 to be effective 10/24/2023.
Filed Date: 8/25/23.
Accession Number: 20230825–5085.
Comment Date: 5 p.m. ET 9/15/23.
Docket Numbers: ER23–2707–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2023–08–25_Tariff Sheet Consolidation True-Up Filing to be effective 6/1/2021.
Filed Date: 8/25/23.
Accession Number: 20230825–5091.
Comment Date: 5 p.m. ET 9/15/23.
Docket Numbers: ER23–2710–000.
Applicants: Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Mid-Atlantic Interstate Transmission, LLC submits tariff filing per 35.13(a)(2)(iii: MAIT submits one Construction Agreement, SA No. 6624 to be effective 10/25/2023.
Filed Date: 8/25/23.
Accession Number: 20230825–5149.
Comment Date: 5 p.m. ET 9/15/23.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR23–3–000.
Applicants: North American Electric Reliability Corporation.
Description: Request of North American Electric Reliability Corporation for Acceptance of 2024 Business Plans and Budgets of NERC and Regional Entities and for Approval of Proposed Assessments to Fund Budgets.
Filed Date: 8/24/23.
Accession Number: 20230824–5178.
Comment Date: 5 p.m. ET 9/14/23.

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.

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Dated: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18867 Filed 8–30–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2610–012; Project No. 2587–066]

Northern States Power Company; Notice of Scoping Meetings and Environmental Site Reviews and Soliciting Scoping Comments

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection.

a. *Type of Applications:* Subsequent Minor (P–2610–012), New Major License (P–2587–066).

b. *Project Nos.:* P–2610–012 and P–2587–066.

c. *Date Filed:* December 30, 2022.

d. *Applicant:* Northern States Power Company, a Wisconsin Corporation.

e. *Names of Projects:* Saxon Falls Hydroelectric Project (Saxon Project) and Superior Falls Hydroelectric Project (Superior Project).

f. *Location:* The projects are located on the Montreal River in Gogebic County, Michigan and Iron County, Wisconsin near the cities of Ironwood, Michigan and Hurley, Wisconsin.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Matthew Miller, Hydro License Consultant, Northern States Power Company, 1414 West Hamilton Avenue, P.O. Box 8, Eau Claire, Wisconsin 54702–0008; telephone at (715) 737–1353 or email at *matthew.j.miller@xcelenergy.com.*

i. *FERC Contact:* Nicholas Ettema, telephone at (312) 596–4447; or email at *nicholas.ettema@ferc.gov.*

j. *Deadline for filing scoping comments:* October 28, 2023.

The Commission strongly encourages electronic filing. Please file scoping comments using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. All filings must clearly identify the following on the first page: Saxon Project No. 2610–012, and/or Superior Project No. 2587–066.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. The applications are not ready for environmental analysis at this time.

l. *Project Descriptions:*

Saxon Project

The Saxon Project consists of an Ambursen-type buttress concrete dam that includes: (1) a 250-foot-long non-overflow earthen embankment; (2) a 57-foot-long non-overflow concrete section; (3) a 31-foot-long non-overflow concrete section with a 19-foot-long, 36.6-foot-high intake structure equipped with a flap gate and a trashrack with 1-inch clear bar spacing; (4) a 30-foot-long concrete section with a 13-foot-high steel Tainter gate; (5) a 127-foot-long spillway section with a crest elevation of 997.0 feet National Geodetic Vertical Dam of 1929 (NGVD 29); and (6) a 23.5-foot-long north abutment section.

The Saxon Project's dam creates an impoundment with a surface area of approximately 70 acres at an elevation of 997.0 feet NGVD 29. From the impoundment, water flows through the intake structure to a 1,607-foot-long steel conduit, a surge tank, and two steel penstocks. From the penstocks, water is conveyed to a powerhouse that contains two 750-kilowatt (kW) horizontal turbine-generator units, for a total installed capacity of 1,500 kW. Water is discharged from the powerhouse directly to the Montreal River. The Saxon Project creates an approximately 2,400-foot-long bypassed reach of the Montreal River. A minimum flow pipe extends from the 31-foot-long non-overflow section of the dam to provide flow to the bypassed reach.

Electricity generated at the powerhouse is transmitted to the electric grid via an approximately 1,000-foot-long, 2.4-kilovolt (kV) overhead transmission line, a 2.4/34.5-kV step-up transformer, and a 12-mile-long, 34.5-kV transmission line.

Project recreation facilities include: (1) a canoe take-out site, boat ramp, and parking area on the southern shore of the impoundment; and (2) a tailwater access site and parking area on the southern shoreline of the Montreal River, opposite of the powerhouse.

Northern States Power operates the project in run-of-river mode, such that project outflow approximates inflow to the impoundment. The current license requires Northern States Power to: (1) minimize fluctuations of the impoundment surface elevation; (2) maintain a minimum impoundment elevation of 997.0 feet NGVD 29 from ice-out through June 1 each year; and (3) from June 2 through ice-out, maintain an impoundment elevation between a minimum of 996.5 and a maximum of 997.0 feet NGVD 29. The current license also requires Northern States Power to release a minimum flow of 5 cubic feet per second (cfs) or inflow, whichever is less, to the bypassed reach from ice-out through October 31 (ice-free season) each year, to protect aquatic and aesthetic resources. The average annual energy production of the Saxon Project from 2017 through 2021 was 10,015.3 MWh.

Northern States Power proposes to revise the Saxon Project boundary around the impoundment to follow a contour elevation of 997.0 feet NGVD 29, which would result in a reduction in the total acreage of the project boundary upstream of the project dam, from 159 acres to 71.7 acres. Additionally, Northern States Power proposes to add 2.7 acres of land to the project boundary near the dam and remove 20 acres of land from the project boundary along the bypassed reach and river downstream of the powerhouse.

Northern States Power proposes to continue operating the Saxon Project in run-of-river mode and maintain water surface elevations as described above with the exception of the maximum impoundment elevation of the Saxon Project from June 2 through ice-out. In addition, Northern States Power proposes to release a minimum aesthetic flow of 5 cfs or inflow, whichever is less, from the Saturday before Memorial Day to October 15, except on weekends and holidays, when a minimum aesthetic flow of 10 cfs or inflow, whichever is less, would be released from 8:00 a.m. to 8:00 p.m.

Superior Project

The Superior Project consists of an Ambursen-type buttress concrete dam that includes: (1) a west abutment section; (2) a 45-foot-long section with a 41.4-foot-long west spillway; (3) a 22-foot-long section with a west steel Tainter gate; (4) an 18.6-foot-long section with an 11.5-foot-long east ogee spillway section with a crest elevation of 740.2 feet NGVD 29, and two sluice gates; (5) a 40.5-foot-long section with two 16-foot-long, 18-foot-high east steel Tainter gates; (6) a 70-foot-long non-overflow section with a 23-foot-long, 29.25-foot-high intake structure equipped with a timber headgate and a trashrack with 1-inch clear bar spacing; and (7) an east abutment section.

The Superior Project's dam creates an impoundment with a surface area of 16.3 acres at an elevation of 740.2 feet NGVD 29. From the impoundment, water flows through the intake structure to a 7-foot-diameter, 1,697-foot-long concrete conduit, a 28-foot-diameter, 41-foot-high concrete and steel surge tank, and two 4.5-foot-diameter, 207-foot-long steel penstocks. From the penstocks, water is conveyed to a 32-foot-long, 62-foot-wide concrete powerhouse that contains two 825-kW horizontal Francis turbine-generator units, for a total installed capacity of 1,650 kW. Water is discharged from the powerhouse to an approximately 80-foot-long, 55-foot-wide tailrace. The Superior Project creates an approximately 1,900-foot-long bypassed reach of the Montreal River.

Electricity generated at the powerhouse is transmitted to the electric grid via a 200-foot-long, 2.4-kV overhead transmission line and a 2.4/34.5-kV step-up transformer located in a substation approximately 150 feet west of the powerhouse.

Recreation facilities at the Superior Project include: (1) a canoe take-out site and an associated 5-vehicle parking area on the western shoreline of the impoundment, approximately 1,050 feet upstream of the dam; (2) a scenic overlook site on the eastern shoreline of the bypassed reach, approximately 480 feet upstream of the tailrace; (3) a fishing area on the eastern shoreline of the tailrace; and (4) a parking area and access trails for the scenic overlook and fishing area.

Northern States Power proposes to reduce the total acreage of the project boundary upstream of the project dam from 296.4 acres to 22.2 acres. Additionally, Northern States Power proposes to add 3.9 acres of land near the powerhouse to the project boundary, remove 35 acres of land east of State Highway 122, and remove 11.1 acres of land along the bypassed reach.

Northern States Power proposes to continue operating the Superior Project in run-of-river mode and maintain water surface elevations and minimum flows as described above.

m. Copies of the applications can be viewed on the Commission's website at *https://www.ferc.gov* using the ''eLibrary'' link. Enter the project's docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support.

You may also register at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov.*

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.*

n. *Scoping Process:* Pursuant to the National Environmental Policy Act (NEPA), Commission staff intends to prepare either an environmental assessment (EA) or an environmental impact statement (EIS) (collectively referred to as the ''NEPA document'') that describes and evaluates the probable effects, including an assessment of the site-specific and cumulative effects, if any, of the proposed action and alternatives. The Commission's scoping process will help determine the required level of analysis and satisfy the NEPA scoping requirements, irrespective of whether the Commission issues an EA or an EIS.

Scoping Meetings

Commission staff will hold two public scoping meetings for the projects to receive input on the scope of the environmental issues that should be analyzed in the NEPA document. An evening meeting will be held at 7:00 p.m. on September 27, 2023, at the City Hall of Hurley, Wisconsin, and will focus on receiving input from the public. A daytime meeting will be held at 9:00 a.m. on September 28, 2023, at the same location, and will focus on the concerns of resource agencies, non-governmental organizations (NGOs), and Indian Tribes. We invite all interested agencies, Indian Tribes, non-governmental organizations, and individuals to attend one or both of these meetings. The times and locations of these meetings are as follows:

Evening Scoping Meeting

Date: Wednesday, September 27, 2023
Time: 7:00 p.m. (CDT)
Place: City Hall of Hurley
Address: 405 5th Avenue North, Hurley, WI 54534

Daytime Scoping Meeting

Date: Thursday, September 28, 2023
Time: 9:00 a.m. (CDT)
Place: City Hall of Hurley
Address: 405 5th Avenue North, Hurley, WI 54534

Copies of the Scoping Document (SD1) outlining the proposed project and subject areas to be addressed in the NEPA document were distributed to the parties on the Commission's mailing list. Copies of the SD1 will be available at the scoping meeting or may be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link (see item m above).

Environmental Site Reviews

The applicant and Commission staff will conduct environmental site reviews of the projects. All interested individuals, agencies, Indian Tribes, and NGOs are invited to attend. All participants are responsible for their own transportation to the sites and during the site visits. Please RSVP via email to *matthew.j.miller@xcelenergy.com* or notify Matthew Miller at 715–737–1353 on or before *Friday, September 22, 2023,* if you plan to attend the environmental site reviews. The times and locations of the environmental site reviews are as follows:

Saxon Falls and Superior Falls Hydroelectric Projects

Date: Wednesday, September 27, 2023
Time: 10:00 a.m. (CDT)
Place: Superior Falls Hydroelectric Project

Participants will meet at the Superior Falls parking lot for the powerhouse of the Superior Project, which is located on Lake Superior Rd, immediately adjacent to the west side of Lake County Park (Latitude 46.56494/Longitude-90.41523). Immediately following the site review at the Superior Project, participants will proceed to the Saxon Project. All participants are responsible for their own transportation and must wear sturdy, closed-toe shoes, or boots.

Objectives

At the scoping meetings, Commission staff will: (1) summarize the environmental issues tentatively identified for analysis in the NEPA document; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue; (3) encourage statements from experts and the public on issues that should be analyzed in the NEPA document, including viewpoints in opposition to, or in support of, the staff's preliminary views; (4) determine the resource issues to be addressed in the NEPA document; and (5) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis.

Procedures

The meetings are recorded by a stenographer and become part of the formal record of the Commission proceeding on the project. Individuals, NGOs, Indian Tribes, and agencies with environmental expertise and concerns are encouraged to attend the meeting and to assist the staff in defining and clarifying the issues to be addressed in the NEPA document.

Dated: August 25, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18872 Filed 8–30–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Boulder Canyon Project

AGENCY: Western Area Power Administration (WAPA), Department of Energy (DOE).

ACTION: Notice concerning fiscal year (FY) 2024 base charge and rates for Boulder Canyon Project (BCP) electric service.

SUMMARY: The Deputy Secretary confirms, approves, and places into effect on a final basis the Boulder Canyon Project base charge and rates for fiscal year 2024 under Rate Schedule BCP–F11. The base charge increased 11.3 percent from $66.8 million in FY 2023 to $74.3 million in FY 2024. The change is primarily the result of an increase in the Bureau of Reclamation's (Reclamation) replacement costs, an increase in WAPA's operations and maintenance (O&M) expenses and replacement costs, and a decrease in prior year carryover funds from FY 2023.

DATES: The FY 2024 base charge and rates are effective October 1, 2023, and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Jack D. Murray, Regional Manager, Desert Southwest Region, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005–6457, or Tina Ramsey, Rates Manager, Desert Southwest Region, Western Area Power Administration, (602) 605–2565, or email: *dswpwrmrk@wapa.gov.*

SUPPLEMENTARY INFORMATION: On March 31, 2023, the Federal Energy Regulatory Commission (FERC) approved and confirmed Rate Schedule BCP–F11, under Rate Order No. WAPA–204, on a final basis through September 30, 2027.[1] WAPA published a **Federal Register** notice (Proposed FRN) on April 18, 2023 (88 FR 23669), proposing the FY 2024 base charge and rates under Rate Schedule BCP–F11. The Proposed FRN also initiated a 90-day public consultation and comment period and

[1] Order Confirming and Approving Rate Schedule on a Final Basis, FERC Docket No. EF22–4–000 (2023).

set forth the date and location of the public information and public comment forums.

The proposed FY 2024 base charge was a 3.5 percent increase over the FY 2023 base charge. In addition, due to recent favorable hydrology projections and following BCP contractor comments during the public consultation and comment period, additional funding of $5.5 million has been reallocated from future years to the FY 2024 budget to accelerate Reclamation's cylinder gate stem replacement project and continue WAPA's relay and breaker replacement project. These factors will increase the base charge 11.3 percent from $66.8 million in FY 2023 to $74.3 million in FY 2024.

The rate-setting methodology for BCP electric service requires a calculation of an annual base charge rather than a unit rate for Hoover Dam hydropower. The base charge recovers an annual revenue requirement that includes projected costs of investment repayment, interest, operations, maintenance, replacements, payments to states, and Hoover Dam visitor services. Non-power revenue projections such as water sales, Hoover Dam visitor revenue, ancillary services, and late fees help offset these projected costs. Hoover power customers are billed a percentage of the base charge in proportion to their power allocation. Unit rates are calculated for comparative purposes but are not used to determine the charges for electric service.

Rate Schedule BCP–F11 and the BCP Electric Service Contract require WAPA to calculate the annual base charge and rates for the next fiscal year before October 1 of each year. The FY 2023 BCP base charge and rates expire on September 30, 2023.

Comparison of Base Charge and Rates

	FY 2023	FY 2024	Amount change	Percent change
Base Charge ($)	66,798,560	74,334,285	7,535,725	11.3
Composite Rate (mills/kWh)	22.43	23.10	0.67	3.0
Energy Rate (mills/kWh)	11.22	11.55	0.33	2.9
Capacity Rate ($/kW-Mo)	2.17	2.15	−0.02	−0.9

Reclamation's FY 2024 budget is increasing $3.3 million from $84.7 million to $88 million, a 3.9 percent increase from FY 2023. Reflected in this budget, O&M costs are decreasing by $811,000 primarily due to the elimination of three positions and the associated travel and training costs. This decrease in O&M costs includes a mid-year review adjustment of $300,000, resulting from changing the financial audit period from every three years to every five years, thereby postponing the FY 2024 audit until FY 2026. Replacement costs are increasing by $3.3 million in FY 2024 due to continuing the unit control modernization, 480-volt switchgear, and the cylinder gate stem replacement projects. Post-retirement benefits costs are increasing $104,000 based on a higher five-year average of recent actual expenses. Visitor services costs are increasing by $728,000, primarily due to costs for the National Park Services security agreement being realigned from security forces in O&M to visitor services.

WAPA's FY 2024 budget is increasing $850,000 to $9.6 million, a 9.7 percent increase from FY 2023. WAPA's O&M costs are increasing $680,000 from FY 2023 due to higher labor projections for salaries, overtime, overhead, and benefits and an updated charging methodology from overhead to direct charging for power billing. WAPA's replacement costs are increasing $130,000 from FY 2023 due to the continuation of the relay and breaker replacement project. WAPA's post-retirement benefit costs are increasing $39,000 from FY 2023 due to a higher five-year average of recent actual expenses.

Costs for Reclamation and WAPA are offset by a slight increase of $18,000 in non-power revenue projections, resulting from a higher estimate for ancillary services. Prior year carryover is projected to be $2.2 million, a $3.4 million decrease from FY 2023.

The proposed FY 2024 base charge for BCP electric service is projected to increase from $66.8 million in FY 2023 to $74.3 million in FY 2024, an 11.3 percent increase. The composite rate is increasing 3 percent and the energy rate is increasing 2.9 percent. The capacity rate is decreasing 0.9 percent from FY 2023, due to increases in capacity forecasts. These unit rate calculations use forecasted energy and capacity values. With the uncertainty of hydrological conditions, Reclamation and Desert Southwest Region (DSW) will continue to work collaboratively to lessen the impact of the ongoing drought in the Colorado River Basin in subsequent years.

Public Notice and Comment

DSW followed the Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions (10 CFR part 903) and General Regulations for the Charges for the Sale of Power from the BCP (10 CFR part 904). DSW took the following steps to involve interested parties in the rate process:

1. DSW provided a website where information is posted about this rate process. The website is located at *www.wapa.gov/regions/DSW/Rates/Pages/boulder-canyon-rates.aspx.*

2. On April 18, 2023, a **Federal Register** notice (88 FR 23669) announced the proposed FY 2024 base charge and rates and initiated the 90-day public consultation and comment period.

3. On April 18, 2023, DSW notified contractors and interested parties of the proposed rates and provided a copy of the published Proposed FRN by email.

4. On May 18, 2023, DSW held a public information forum via video conference. This provided contractors and interested parties an opportunity to provide official comments for the record.

5. On June 13, 2023, DSW posted on its website responses to questions asked at the public information forum about Reclamation's Supplemental Environmental Impact Statement, the Western Energy Imbalance Market, and the Colorado River Storage Project's potential participation in the Southwest Power Pool's Western Regional Transmission Organization.

6. On June 20, 2023, DSW held a public comment forum via video conference. This provided contractors and interested parties an opportunity to provide official comments for the record.

7. During the 90-day consultation and comment period, which ended on July 17, 2023, DSW received comments from 17 contractors and interested parties. DSW's responses to questions received prior to the public comment forum were posted to the BCP website. DSW's responses to comments received during or after the public comment forum appear below, paraphrased where

appropriate without compromising their meaning.

Comment: At the public comment forum, five contractors and interested parties expressed support for increasing Reclamation and WAPA's replacement budgets for FY 2024. Following a special session of the BCP Engineering and Operating Committee on June 29, 2023, a summary of which is provided on DSW's website, 11 additional contractors and interested parties expressed support for increasing Reclamation and WAPA's replacement budgets by moving costs associated with Reclamation's cylinder gate stem project in the amount of $4.5 million and WAPA's relay and breaker replacement projects in the amount of $950,000 from future years into FY 2024. Commenters stated they are aware the acceleration of these projects will increase the FY 2024 base charge and rates. Commenters further noted the favorable hydrology projections for FY 2024 provide an opportunity to complete some needed maintenance, reduce the total cost of the projects, and should put downward pressure on the rates in subsequent years.

Response: Reclamation and WAPA appreciate the comments and the support on the acceleration of Reclamation's cylinder gate stem project and the continuation of WAPA's relay and breaker replacement project. The costs associated with these projects have been moved from future years and will be included in the FY 2024 budget, base charge, and rates.

Comment: One commenter expressed concerns about future work plans, maintaining and operating the Hoover Dam visitor center, and the decreasing Hoover Dam visitor center revenues. The commenter would like Reclamation and WAPA to continue their efforts to mitigate the effects on the base charge and rates and for Reclamation to consider making changes to the visitor center.

Response: Reclamation and WAPA acknowledge the comment and will continue to work collaboratively with the contractors on moderating future costs and mitigating the effects on the base charge and rates to ensure rates are the lowest possible consistent with sound business principles.

Comment: One commenter also requested that future energy and capacity projections be considered as alternative sets of data for future rate analysis.

Response: Reclamation and WAPA agree with this request to consider alternative data sets in future rate analysis and will work to incorporate the data in future meetings.

Certification of Rates

WAPA's Administrator certified the FY 2024 base charge and rates under Rate Schedule BCP–F11 are the lowest possible rates consistent with sound business principles. The base charge and rates were developed following administrative policies and applicable laws.

Availability of Information

Information used by WAPA to develop the base charge and rates for electric service is available for inspection and copying at the Desert Southwest Customer Service Regional Office, located at 615 South 43rd Avenue, Phoenix, Arizona. Many of these documents are also available on DSW's website at *www.wapa.gov/regions/DSW/Rates/Pages/boulder-canyon-rates.aspx.*

Legal Authority

DOE regulations governing charges for the sale of BCP power, 10 CFR 904.7(e), require annual review of the BCP base charge and an ''adjust[ment], either upward or downward, when necessary and administratively feasible, to assure sufficient revenues to effect payment of all costs and financial obligations associated with the [p]roject.'' WAPA's Administrator provided all BCP contractors an opportunity to comment on the proposed base charge adjustment, consistent with DOE procedures for public participation in rate adjustments. The BCP Electric Service Contract states for years other than the first year and each fifth year thereafter, when the rate schedule is approved by the Deputy Secretary on a provisional basis and by FERC on a final basis, adjustments to the base charge ''shall become effective upon approval by the Deputy Secretary of Energy.'' Accordingly, the Deputy Secretary of Energy may approve the FY 2024 base charge and rates for BCP electric service, as authorized by the BCP Electric Service Contract and DOE's procedures for public participation in rate adjustments set forth at 10 CFR parts 903 and 904.[2]

Following DOE's review of WAPA's proposal, and as authorized by applicable provisions of the BCP Electric Service Contract, I have confirmed, approved, and placed the FY 2024 base charge and rates for BCP electric service, under Rate Schedule BCP F–11, into effect on a final basis through September 30, 2024.

[2] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

Ratemaking Procedure Requirements

Environmental Compliance

WAPA has determined that this action fits within the following categorical exclusions listed in appendix B to subpart D of 10 CFR 1021: B4.3 (Electric power marketing rate changes). Categorically excluded projects and activities do not require preparation of either an environmental impact statement or an environmental assessment.[3] A copy of the categorical exclusion determination is available on WAPA's website at *www.wapa.gov/regions/DSW/Environment/Pages/environment.aspx.*

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Signing Authority

This document of the Department of Energy was signed on August 25, 2023, by David M. Turk, Deputy Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 28, 2023.

Treena V. Garrett,

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

[FR Doc. 2023–18849 Filed 8–30–23; 8:45 am]

BILLING CODE 6450–01–P

[3] The determination was done in compliance with NEPA (42 U.S.C. 4321–4347); the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2023–0015; FRL–11225–01–OCSPP]

Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted or denied emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The exemptions or denials were granted during the period April 1, 2023, to June 30, 2023, to control unforeseen pest outbreaks.

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).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed at the end of the emergency exemption or denial.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2023–0015, 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. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

II. Background

EPA has granted or denied emergency exemptions to the following State and Federal agencies. The emergency exemptions may take the following form: Crisis, public health, quarantine, or specific. EPA has also listed denied emergency exemption requests in this notice.

Under FIFRA section 18 (7 U.S.C. 136p), EPA can authorize the use of a pesticide when emergency conditions exist. Authorizations (commonly called emergency exemptions) are granted to State and Federal agencies and are of four types:

1. A ''specific exemption'' authorizes use of a pesticide against specific pests on a limited acreage in a particular State. Most emergency exemptions are specific exemptions.

2. ''Quarantine'' and ''public health'' exemptions are emergency exemptions issued for quarantine or public health purposes. These are rarely requested.

3. A ''crisis exemption'' is initiated by a State or Federal agency (and is confirmed by EPA) when there is insufficient time to request and obtain EPA permission for use of a pesticide in an emergency.

EPA may deny an emergency exemption: If the State or Federal agency cannot demonstrate that an emergency exists, if the use poses unacceptable risks to the environment, or if EPA cannot reach a conclusion that the proposed pesticide use is likely to result in ''a reasonable certainty of no harm'' to human health, including exposure of residues of the pesticide to infants and children.

If the emergency use of the pesticide on a food or feed commodity would result in pesticide chemical residues, EPA establishes a time-limited tolerance meeting the ''reasonable certainty of no harm standard'' of the Federal Food, Drug, and Cosmetic Act (FFDCA).

In this document: EPA identifies the State or Federal agency granted the exemption or denial, the type of exemption, the pesticide authorized and the pests, the crop or use for which authorized, number of acres (if applicable), and the duration of the exemption. EPA also gives the **Federal Register** citation for the time-limited tolerance, if any.

III. Emergency Exemptions and Denials

U.S. States and Territories

Arizona

Department of Agriculture

Specific exemption: EPA authorized the co-formulated use of thiamethoxam and lambda-cyhalothrin on a maximum of 400 acres of guayule to control palestriped flea beetle. A time-limited tolerance in connection with this action was not established since the emergency use is non-food/feed. The authorization was effective May 12, 2023.

Colorado

Department of Agriculture

Denial: On May 18, 2023, EPA denied a specific exemption request for the use of metamitron to control glyphosate-resistant Palmer amaranth in sugar beets. Metamitron is an unregistered pesticide and EPA has not yet fully evaluated its potential risks. Therefore, this request was denied because the Agency was unable to make the safety findings for metamitron as mandated by FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA).Because an unregistered pesticide was requested, a Notice of Receipt, with opportunity for public comment (required by 40 CFR 166.24), published in the **Federal Register** on March 10, 2023 (88 FR 15014) (FRL–10772–01–OCSPP). The public comment period closed on March 27, 2023. No negative comments were submitted, but a number of comments were received from stakeholders (*e.g.* producers, grower representatives, and state government entities) in favor of allowing the use.

Hawaii

Department of Agriculture

Specific exemptions: EPA authorized the use of *Wolbachia pipientis* DQB strain (wAlbB) contained in live adult male *culex quinquefasciatus* mosquitoes on a maximum of 20,000 acres of State, Federal, and private lands to control mosquitoes (*Cx. quinquefasciatus*). The authorization was effective April 25, 2023.

EPA authorized the co-formulated use of fluxapyroxad and pyraclostrobin on a maximum of 8,000 acres of coffee to control coffee leaf rust. Import tolerances in connection with prior registration actions are established in 40 CFR 180.666 for fluxapyroxad and 40 CFR 180.582 for pyraclostrobin and are sufficient to support this use. The authorization was effective May 18, 2023.

Michigan

Department of Agriculture and Rural Development

Specific Exemption: EPA authorized the use of acifluorfen on a maximum of 48,000 acres of sugar beets for postemergence control of invasive *amaranthus* (pigweed) spp., waterhemp, and palmer amaranth. Time-limited tolerances in connection with a previous action support this emergency use and are established in 40 CFR 180.383(b). The authorization was effective May 4, 2023

Minnesota

Department of Agriculture

Specific exemption: EPA authorized the use of acifluorfen on a maximum of 65,000 acres of sugar beets for postemergence control of glyphosate-resistant waterhemp. Time-limited tolerances in connection with a previous action support this emergency use and are established in 40 CFR 180.383(b). The authorization was effective May 4, 2023.

Nebraska

Department of Agriculture

Denial: On May 18, 2023, EPA denied a specific exemption request for the use of metamitron to control glyphosate-resistant Palmer amaranth in sugar beets. Metamitron is an unregistered pesticide and EPA has not yet fully evaluated its potential risks. Therefore, the request was denied because the Agency was unable to make the safety findings for metamitron as mandated by FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). Because an unregistered pesticide was requested, a Notice of Receipt, with opportunity for public comment (required by 40 CFR 166.24), published in the **Federal Register** on March 10, 2023 (88 FR 15014) (FRL–10772–01–OCSPP). The public comment period closed on March 27, 2023. No negative comments were submitted, but a number of comments were received from stakeholders (*e.g.,* producers, grower representatives, and state government entities) in favor of allowing the use.

North Dakota

Department of Agriculture

Specific exemption: EPA authorized the use of acifluorfen on a maximum of 20,000 acres of sugar beets for postemergence control of glyphosate resistant waterhemp. Time-limited tolerances in connection with a previous action support this emergency use and are established in 40 CFR 180.383(b). The authorization was effective May 4, 2023.

Authority: 7 U.S.C. 136 *et seq.*

Dated: August 24, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2023–18879 Filed 8–30–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2023–0075; FRL–11150–01–OCSPP]

Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw its requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before October 2, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2023–0075, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Christopher Green, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2707; email address: *green.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/comments.html.*

II. What action is the Agency taking?

This notice announces receipt by the Agency of requests from registrants to cancel certain pesticide products registered under FIFRA section 3 (7 U.S.C. 136a) or 24(c) (7 U.S.C. 136v(c)). These registrations are listed in sequence by registration number (or company number and 24(c) number) in Table 1 of this unit.

Unless the Agency determines that there are substantive comments that warrant further review of the requests or the registrants withdraw their requests, EPA intends to issue an order in the **Federal Register** canceling all of the affected registrations.

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Company No.	Product name	Active ingredients
100–1305	100	Cruiser Maxx Cereals	Difenoconazole (128847/119446–68–3)—(3.36%), Metalaxyl-M (113502/70630–17–0)—(.56%), Thiamethoxam (060109/153719–23–4)—(2.8%).
100–1422	100	A16901B Ornamental Insecticide	Cyantraniliprole (090098/736994–63–1)—(20%), Thiamethoxam (060109/153719–23–4)—(20%).
100–1544	100	HGW86 T&O Insect Control	Cyantraniliprole (090098/736994–63–1)—(18.66%).
100–1552	100	Mainspring	Cyantraniliprole (090098/736994–63–1)—(18.66%).
100–1574	100	Mainspring Flora GH	Cyantraniliprole (090098/736994–63–1)—(10%), Pymetrozine (101103/123312–89–0)—(30%).
264–998	264	Four Way Peanut Seed Treatment Fungicide	Captan (081301/133–06–2)—(49%), Metalaxyl (113501/57837–19–1)—(.8%), Thiophanate-methyl (102001/23564–05–8)—(13.6%), Trifloxystrobin (129112/141517–21–7)—(2%).
56228–33	56228	Mesurol 75% Wettable Powder Aversive Conditioning Egg Treatment.	Methiocarb (100501/2032–65–7)—(75%).
AR–130004	69969	Avipel (Dry) Corn Seed Treatment	Anthraquinone (122701/84–65–1)—(50%).
OR–160005	61842	Linex 4L Herbicide	Linuron (035506/330–55–2)—(40.6%).
TN–090006	264	Gaucho XT Flowable	Imidacloprid (129099/138261–41–3)—(12.7%), Metalaxyl (113501/57837–19–1)—(.82%), Tebuconazole (128997/107534–96–3)—(.62%).
WA–030035	62719	Stinger	Clopyralid, monoethanolamine salt (117401/57754–85–5)—(40.9%).
WA–120008	62719	Entrust SC	Spinosad (110003/131929–60–7)—(22.5%).
WA–970033	62719	Stinger	Clopyralid, monoethanolamine salt (117401/57754–85–5)—(40.9%).

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in this unit.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA company No.	Company name and address
100	Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419–8300.
264	Bayer CropScience, LP, Agent Name: Bayer CropScience, LLC, 801 Pennsylvania Avenue, Suite 900, Washington, DC 20004.
56228	U.S. Department of Agriculture, Animal and Plant Health Inspection Service, 4700 River Road, Unit 149, Riverdale, MD 20737.
61842	Tessenderlo Kerley, Inc., Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street, Ct. NW, Gig Harbor, WA 98332.
62719	Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268.
69969	Arkion Life Sciences, LLC, Agent Name: Wagner Regulatory Associates, Inc., P.O. Box: 640, Hockessin, DE 19707.

III. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or
2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants in Table 2 of Unit II, have requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 30-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation should submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Because the Agency has identified no significant potential risk concerns associated with these pesticide products, upon cancellation of the products identified in Table 1 of Unit II, EPA anticipates allowing registrants to sell and distribute existing stocks of these products for 1 year after publication of

the Cancellation Order in the **Federal Register**.

Thereafter, registrants will be prohibited from selling or distributing the pesticides identified in Table 1 of Unit II, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

Authority: 7 U.S.C. 136 *et seq.*

Dated: August 24, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2023–18814 Filed 8–30–23; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

Sunshine Act Meetings

Notice of Open Meeting of the Advisory Committee of the Export-Import Bank of the United States (EXIM)

TIME AND DATE: Monday, September 11th, 2023, from 2 p.m.–3:30 p.m. EDT.

PLACE: Virtual meeting—The meeting will be virtually for committee members, EXIM's Board of Directors and support staff, and virtually for all other participants.

STATUS: *Public Participation:* The meeting will be open to public participation and time will be allotted for questions or comments submitted online. Members of the public may also file written statements before or after the meeting to *external@exim.gov.* Interested parties may register below for the meeting: *https://events.teams.microsoft.com/event/762a4fb9-53bb-4114-ba3e-11b057cf3527@b953013c-c791-4d32-996f-518390854527.*

MATTERS TO BE CONSIDERED: Discussion of EXIM policies and programs to provide competitive financing to expand United States exports and comments for inclusion in EXIM's Report to the U.S. Congress on Global Export Credit Competition.

CONTACT PERSON FOR MORE INFORMATION: For further information, contact India Walker, Senior External Engagement Specialist, at 202–480–0062 or at *india.walker@exim.gov.*

Joyce B. Stone,

Assistant Corporate Secretary.

[FR Doc. 2023–18903 Filed 8–29–23; 11:15 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

Sunshine Act Meetings

Notice of Open Meeting of the Sub-Saharan Africa Advisory Committee of the Export-Import Bank of the United States (EXIM)

TIME AND DATE: Monday, September 11th, 2023, from 2 p.m.–3:30 p.m. EDT.

PLACE: Virtual meeting—The meeting will be virtually for committee members, EXIM's Board of Directors and support staff, and virtually for all other participants.

STATUS: *Public Participation:* The meeting will be open to public participation and time will be allotted for questions or comments submitted online. Members of the public may also file written statements before or after the meeting to *external@exim.gov.* Interested parties may register below for the meeting: *https://events.teams.microsoft.com/event/762a4fb9-53bb-4114-ba3e-11b057cf3527@b953013c-c791-4d32-996f-518390854527.*

MATTERS TO BE CONSIDERED: Discussion of EXIM policies and programs designed to support the expansion of financing support for U.S. manufactured goods and services in Sub-Saharan Africa.

CONTACT PERSON FOR MORE INFORMATION: For further information, contact India Walker, Senior External Engagement Specialist, at 202–480–0062 or at *india.walker@exim.gov.*

Joyce B. Stone,

Assistant Corporate Secretary.

[FR Doc. 2023–18904 Filed 8–29–23; 11:15 am]

BILLING CODE 6690–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings

TIME AND DATE: 12:02 p.m. on Tuesday, August 29, 2023.

PLACE: The meeting was held in the Board Room located on the sixth floor of the FDIC Building located at 550 17th Street NW, Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The Board of Directors of the Federal Deposit Insurance Corporation met to consider matters related to the Corporation's supervision, corporate, and resolution activities. In calling the meeting, the Board determined, on motion of Vice Chairman Travis J. Hill, seconded by Director Jonathan P. McKernan, and concurred in by Director Rohit Chopra (Director, Consumer Financial Protection Bureau), Director Michael J. Hsu (Acting Comptroller of the Currency), and Chairman Martin J. Gruenberg, that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B).

CONTACT PERSON FOR MORE INFORMATION: Requests for further information concerning the meeting may be directed to Debra A. Decker, Executive Secretary of the Corporation, at 202–898–8748.

Dated this the 29th day of August, 2023.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2023–18988 Filed 8–29–23; 4:15 pm]

BILLING CODE 6714–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0157; Docket No. 2023–0053; Sequence No. 7]

Information Collection; Architect-Engineer Qualifications (SF–330)

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, DoD, GSA, and NASA invite the public to comment on an extension concerning architect-engineer qualifications (Standard Form (SF) 330). DoD, GSA, and NASA invite comments on: whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or

other forms of information technology. OMB has approved this information collection for use through February 29, 2024. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD, GSA, and NASA will consider all comments received by October 30, 2023.

ADDRESSES: DoD, GSA, and NASA invite interested persons to submit comments on this collection through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

Instructions: All items submitted must cite OMB Control No. 9000–0157, Architect-Engineer Qualifications (SF–330). Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0157, Architect-Engineer Qualifications, SF–330.

B. Need and Uses

This clearance covers the information that offerors must submit to comply with the following Federal Acquisition Regulation (FAR) requirement:

Standard Form (SF) 330, Architect-Engineer Qualifications. As specified in FAR 36.702(b), an architect-engineer firm must provide information about its qualifications for a specific contract when the contract amount is expected to exceed the simplified acquisition threshold (SAT).

Part I—Contract-Specific Qualifications. The information on the form is reviewed by a selection panel composed of professionals and assists the panel in selecting the most qualified architect-engineer firm to perform the specific project. The form is designed to provide a uniform method for architect-engineer firms to submit information on experience, personnel, and capabilities of the architect-engineer firm to perform along with information on the consultants they expect to collaborate with on the specific project. Part I of the SF 330 may be used when the contract amount is expected to be at or below the SAT, if the contracting officer determines that its use is appropriate.

Part II—General Qualifications. The information obtained on this form is used to determine if a firm should be solicited for architect-engineer projects. Architect-engineer firms are encouraged to update the form annually. Part II of the SF 330 is used to obtain information from an architect-engineer firm about its general professional qualifications.

The SF 330 accomplishes the following:

- Expands essential information about qualifications and experience data including:
  - ❖ An organizational chart of all participating firms and key personnel.
  - ❖ For all key personnel, a description of their experience in 5 relevant projects.
  - ❖ A description of each example project performed by the project team (or some elements of the project team) and its relevance to the agency's proposed contract.
  - ❖ A matrix of key personnel who participated in the example projects. This matrix graphically illustrates the degree to which the proposed key personnel have worked together before on similar projects.
- Reflects current architect-engineer disciplines, experience types and technology.
- Permits limited submission length thereby reducing costs for both the architect-engineer industry and the Government. Lengthy submissions do not necessarily lead to a better decision on the best-qualified firm. The proposed SF 330 indicates that agencies may limit the length of a firm's submissions, either certain sections or the entire package. The Government's right to impose such limitations was established in case law (Coffman Specialties, Inc., B–284546. N–284546/2, 2000 U.S. Comp. Gen. LEXIS 58, May 10, 2000).

The contracting officer uses the information provided on the SF 330 to evaluate firms to select an architect-engineer firm for a contract.

C. Annual Burden

Respondents: 682.
Total Annual Responses: 2,728.
Total Burden Hours: 79,112.
Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0157, Architect-Engineer Qualifications (SF–330).

Janet Fry,
Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2023–18843 Filed 8–30–23; 8:45 am]
BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 5 U.S.C. 1009(d), 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, and the Determination of the Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel; (SEP)–RFA–OH–22–003, Occupational Safety and Health Training Project Grants.

Date: November 30, 2023.

Time: 1 p.m.–5 p.m., EST.

Place: Video-Assisted Meeting.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Marilyn Ridenour, B.S.N., M.P.H., Scientific Review Official, Office of Extramural Programs, Centers for Disease Control and Prevention, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone: (304) 285–5879; Email: *MRidenour@cdc.gov.*

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–18806 Filed 8–30–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0940]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 2, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0500. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Rapid Response Surveys

OMB Control Number 0910–0500—Extension

This generic information collection supports research conducted by FDA, as authorized under section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

FDA is requesting extension of OMB approval to conduct rapid response surveys (RRS). Through these surveys, FDA seeks to determine whether a problem impacts the public health and to quickly obtain vital information about risks and interventions. FDA will use the information gathered from these surveys to make quick turnaround decisions about safety problems or risk management solutions so the Agency may take appropriate public health action including dissemination of information as necessary. Participation in these surveys is voluntary.

Respondents may include manufacturers and distributors of biologics, drugs, food, animal food and drugs, dietary supplements, food additives, cosmetics, medical devices, and tobacco products; distributors; sponsors and importers; consumers; healthcare professionals; hospitals; specialized medical facilities (*e.g.,* cardiac surgery, obstetrics/gynecology services, pediatric services, etc.) and other user facilities including nursing homes, ambulatory surgical and outpatient diagnostic and treatment facilities when FDA must quickly determine whether or not a problem impacts the public health. Once FDA understands the need for additional surveillance data to address a potential public health hazard, the appropriate respondents will be identified for each unique RRS.

In the **Federal Register** of April 20, 2023 (88 FR 24423), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment, which was generally supportive of FDA's use of RRS. (Comment) The comment suggested that FDA ''authorize, develop, and implement a mechanism that provides States and the most local level of public health departments immediate notification and access to RRS results when the FDA issues a RRS wholly or partially in their areas of jurisdiction.'' (Response) FDA already has in place mechanisms to share pertinent health information with State, local, and tribal authorities. We currently share aggregated data (without personally identifiable information) of hospital reporting RRS. However, FDA's use of RRS has not recently developed data about potential safety problems or risk management solutions that would require development of a new mechanism for immediate notification and access to RRS results. For example, FDA used a RRS to identify and maintain a list of drugs essential for the care and management of hospitalized patients with COVID–19, particularly for ventilated patients in the intensive care units. FDA used the information to help to identify drugs that may be at risk of a regional or national shortage, and to help ensure these drugs remain available to meet the needs of our nation. FDA also used a RRS to engage stakeholders when developing the food safety surveillance sampling assignments. FDA shared information with key external stakeholders on the hot pepper and cucumber sampling assignments and garnered industry feedback through survey questions to ensure that sample collection is done as effectively and efficiently as possible. Neither of these surveys developed information that would require development of a new mechanism for immediate notification and access to RRS results. The latest update survey data from FDA can be found here: *https://www.fda.gov/science-research/fda-science-forum/fda-covid-19-critical-care-drug-monitoring-survey-portal-ongoing-surveillance-critical-drugs-related.* Please also note that if you or your hospital stakeholders are experiencing a drug shortage and need assistance on how to obtain supply, please refer to the information at *Drugshortages@fda.hhs.gov.* FDA Drug Shortage Staff responds to all reports received on a daily basis.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA Rapid Response Surveys	10,000	1	10,000	0.5 (30 minutes)	5,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate that each rapid response survey will take no more than 30 minutes to complete.

Based on a review of the information collection since our last request, we have adjusted our burden estimate which has resulted in a decrease to the currently approved burden. We now estimate one response per respondent which results in a decrease in overall burden of 25,000 hours.

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18832 Filed 8–30–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3136]

Agency Information Collection Activities; Proposed Collection; Comment Request; Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the dispute resolution procedures for science-based decisions on products regulated by the Center for Veterinary Medicine (CVM).

DATES: Either electronic or written comments on the collection of information must be submitted by October 30, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 30, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3136 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://*

www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber 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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine

OMB Control Number 0910–0566—Extension

This information collection supports FDA guidance. Section 562 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–1) directs FDA to establish adequate dispute resolution procedures to ensure appropriate review of scientific controversies between FDA and members of regulated industry. To implement this provision, we amended the general appeal regulation applicable across all FDA components (21 CFR 10.75). At the same time and consistent with the mandates of section 562 of the FD&C Act, we adopted an approach whereby specific implementation procedures regarding scientific controversy associated with review of certain FDA decisions are detailed in center-issued guidance.

The Center for Veterinary Medicine (CVM)'s Guidance for Industry (GFI) #79, ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine'' (*https://www.fda.gov/media/70279/download*), describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. The guidance details information on how CVM intends to apply provisions of existing regulations regarding internal review of Agency decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants, or manufacturers of animal drugs or other products regulated by CVM who wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established procedures discussed in the guidance.

CVM encourages applicants to begin the resolution of science-based disputes with discussions with the review team/group, including the Team Leader or Division Director. The Center prefers that differences of opinion regarding science or science-based policy be resolved between the review team/group and the applicant. If the matter is not resolved by this preferred method, then CVM recommends that the applicant follow the procedures found in GFI #79.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
GFI #79, section IV; Request for review of a scientific dispute	1	4	4	10	40

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18830 Filed 8–30–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3168]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements associated with extralabel drug use in animals.

DATES: Either electronic or written comments on the collection of information must be submitted by October 30, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 30, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3168 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Extralabel Drug Use in Animals—21 CFR 530

OMB Control Number 0910–0325—Extension

This information collection supports FDA's implementation of section 512 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b), which governs new animal drugs. Agency regulations in 21 CFR part 530, permit FDA, if we find that there is a reasonable probability that the extralabel use of an animal drug may present a risk to public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level. This requirement is codified at 21 CFR 530.22(b). Although to date, we

have not established a safe level for a residue from the extralabel use of any new animal drug and, therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal and/or State Agencies, academia, or individuals.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
530.22(b); Submission(s) of analytical method	2	1	2	4,160	8,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18834 Filed 8–30–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1214]

Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products.'' FDA is issuing this guidance as part of its Real-World Evidence (RWE) Program for drugs and to satisfy, in part, the mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance about the use of RWE in regulatory decision making. This guidance discusses the applicability of FDA's investigational new drug application (IND) regulations to various clinical study designs that utilize real-world data (RWD) and clarifies the Agency's expectations regarding clinical studies using RWD submitted to FDA in support of a regulatory decision regarding the effectiveness or safety of a drug that are not subject to the IND regulations. This guidance finalizes the draft guidance of the same title issued on December 9, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on August 31, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–1214 for ''Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not

in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3226, Silver Spring, MD 20993–0002, 301–796–3161, *Dianne.Paraoan@fda.hhs.gov;* or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *Anne.Taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products.'' The guidance discusses the following major topics: (1) applicability of 21 CFR part 312 to studies using RWD and (2) regulatory considerations for non-interventional (observational) studies involving the use of RWD. Regulatory considerations addressed by the guidance include the following: (1) transparency for data collection and analysis, (2) access to RWD, (3) study monitoring, (4) safety reporting, (5) other sponsor responsibilities, and (6) the analysis of RWD generated from the use of a product under an emergency use authorization (EUA) in routine practice.

Section 3022 of the 21st Century Cures Act (Cures Act) of 2016 amended the FD&C Act to add section 505F, Utilizing Real World Evidence (21 U.S.C. 355g), which requires FDA to issue guidance about the use of RWE in regulatory decision-making. In addition, under the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), FDA is committed to publish draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions. In 2018, FDA created an RWE Framework and an RWE Program to evaluate the potential use of RWE to help support the approval of a new indication for a drug already approved under the FD&C Act or to help support or satisfy postapproval study requirements. In late 2021, FDA utilized the RWE Program to issue draft guidances outlining considerations for the use of RWD and RWE in regulatory decision making to satisfy the Cures Act mandate and the PDUFA VI commitment.

This guidance finalizes the draft guidance of the same title issued on December 9, 2021 (86 FR 70131). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include transfer of relevant definitions from the glossary to the text as well as additional language about data generated in clinical practice for products used under an EUA consistent with a mandate under the Food and Drug Omnibus Reform Act of 2022. Clarifying information was also added, including the use of existing regulatory pathways for third parties to provide patient-level data to FDA when a sponsor cannot submit such data to FDA through traditional channels. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

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 Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 11 pertaining to electronic records and signatures have been approved under OMB control number 0910–0303. The collections of information in 21 CFR parts 50 and 56 relating to protection of human subjects and Institutional Review Boards have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 310 relating to postmarketing adverse drug experience reporting have been approved under OMB control number 0910–0230. The collections of information in 21 CFR part 600 for general records and postmarketing adverse experience reporting pertaining to biological products have been approved under OMB control number 0910–0308. The collections of information in 21 CFR parts 310, 314, and 600 pertaining to adverse event and product experience reporting have been approved under OMB control number 0910–0291. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 600 have been approved under OMB control number 0910–0458.

III. Electronic Access

Persons with access to the internet may obtain the guidance at: *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18841 Filed 8–30–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2024]

Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.'' This guidance clarifies the enhanced drug distribution security requirements listed in the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, this guidance outlines and makes recommendations on the system attributes necessary to enable secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary. This guidance finalizes the draft guidance of the same title issued on June 4, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on August 31, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–2024 for ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Abha Kundi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov;* or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.'' The Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) was signed into law on November 27, 2013.

The DSCSA outlines critical steps to achieve electronic pharmaceutical supply chain interoperability by November 27, 2023, that will enhance

the identification and tracing of certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee-1), which established product tracing, product identifier, authorized trading partner, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Section 582 of the FD&C Act also imposed requirements for enhanced drug distribution security that go into effect on November 27, 2023.

Trading partners, along with Federal and State authorities, have an important role in ensuring the quality of prescription drugs and protecting the integrity of the pharmaceutical distribution supply chain. The DSCSA requirements, which have been phased in since 2013, improve supply chain security activities by trading partners involved in prescription drug manufacturing, repackaging, wholesale distribution, warehousing or related logistical activities, and dispensing. The gradual implementation of the DSCSA requirements for product tracing, product identification, authorized trading partners, and verification facilitates the development of electronic interoperability to enhance the security of the pharmaceutical distribution supply chain.

Section 582(g)(1) of the FD&C Act sets forth the requirements for enhanced drug distribution security as of November 27, 2023, including (as described in that provision and generally summarized here):

- The exchange of transaction information and transaction statements in a secure, interoperable, electronic manner.
- Transaction information that includes the product identifier at the package level for each package included in the transaction.
- Systems and processes for verification of product at the package level.
- Systems and processes needed to promptly respond to requests from FDA (or other appropriate Federal or State officials) for product transaction information in the event of a recall or to investigate suspect and illegitimate products.

This guidance clarifies the enhanced drug distribution security requirements and pursuant to section 582(h)(3) of the FD&C Act describes recommendations for system attributes necessary for enhanced product tracing and enhanced verification, including when the use of aggregation and inference may be appropriate.

This guidance finalizes the draft guidance entitled ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act'' issued on June 4, 2021 (86 FR 30053). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include removal of the term ''enhanced system'' when referring to the requirements in section 582(g) of the FD&C Act to avoid confusion and clarification of recommendations addressing (1) reconciliation of transaction information, (2) aggregation and inference, and (3) verification of saleable returns, including a brief discussion of the sunset provisions of section 582(k) of the FD&C Act. Changes also include clarification of requirements for provision of certain information in response to requests stemming from investigation of suspect or illegitimate product. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance includes 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. 3501–3520). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent substantive or material modifications to those previously approved collections of information found in FDA regulations or guidance.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18831 Filed 8–30–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Supporting Healthy Start Performance Project

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Announcing period of performance supplement for the Supporting Healthy Start Performance Project (SHSPP) recipient.

SUMMARY: HRSA will provide supplemental award funds to the current SHSPP recipient, in fiscal year 2023 to provide new and continued support to Healthy Start grant recipients.

FOR FURTHER INFORMATION CONTACT: Rochelle Logan, Healthy Start Team lead, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, Health Resources and Services Administration, at *rlogan@hrsa.gov* or (301) 443–0543.

SUPPLEMENTARY INFORMATION:

Amount of Non-Competitive Award(s): One award for $1,900,000.

Project Period: June 1, 2023, to May 31, 2024.

Assistance Listing (CFDA) Number: 93.926.

Award Instrument: Supplement.

Authority: 42 U.S.C. 254c–8 (title III, section 330H of the Public Health Service Act).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	City, state	Award amount
UF5MC32750	National Institute for Children's Health Quality	Boston, MA	$1,900,000

Justification: HRSA will provide supplemental award funds to the current SHSPP recipient in fiscal year 2023 to provide new and continued support to Healthy Start grant recipients. The current recipient of the SHSPP is best positioned to address the objectives that to be supported by the supplemental funds, including supporting data collection and evaluation and implementing applicable Executive Orders.

Carole Johnson,

Administrator.

[FR Doc. 2023–18798 Filed 8–30–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA-Initiated Supplemental Funding to the Supporting Maternal Health Innovation Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: HRSA is providing supplemental funds not to exceed $1,500,000 to the Supporting Maternal Health Innovation Program, also referred to as the Maternal Health Learning and Innovation Center (MHLIC), in fiscal year (FY) 2023 to provide support and capacity building to HRSA's new maternal health award recipients under the State Maternal Health Innovation (MHI) Program (HRSA–23–108).

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, Chief, Maternal and Women's Health Branch, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, at *ksherman@hrsa.gov* or (301) 443–1702.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: One award to the University of North Carolina at Chapel Hill, the current recipient under the Supporting Maternal Health Innovation Program, now known as MHLIC, as listed in Table 1.

Amount of Non-Competitive Award: Up to $1,500,000.

Project Period: September 30, 2019, to September 29, 2024.

CFDA Number: 93.110.

Award Instrument: Supplement.

Authority: 42 U.S.C. 701(a)(2) (title V, section 501(a)(2) of the Social Security Act).

TABLE 1—SUPPORTING MHI PROGRAM AWARD RECIPIENT (2019–2024)

Grant No.	Grantee organization	City, state	Award amount
U7CMC33636	University of North Carolina at Chapel Hill	Raleigh, NC	$1,500,000

Justification: The Consolidated Appropriations Act, 2023 (Pub. L. 117–328) included additional Special Projects of Regional and National Significance funding. The Explanatory Statement accompanying the Consolidated Appropriations Act specified a $26 million increase for the State MHI Program to establish new cooperative agreements in FY 2023 with up to 23 new states. MHLIC provides support and capacity building to HRSA's maternal health award recipients. Supplemental funds to MHLIC will be used to provide support and capacity building to the new cohort of FY 2023 State MHI award recipients. The requested activities are within scope of the Supporting Maternal Health Innovation Program.

Carole Johnson,

Administrator.

[FR Doc. 2023–18799 Filed 8–30–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK SEP High Risk Multi-Center Clinical Study Cooperative Agreement U01.

Date: September 28, 2023.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cheryl Nordstrom, Ph.D., MPH, Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7013, Bethesda, MD 20892, 301–402–6711, *cheryl.nordstrom@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 28, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18836 Filed 8–30–23; 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: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Cellular, Molecular, and Immunobiology Study Section.

Date: September 26–27, 2023.

Time: 8:00 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: George M Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301–435–0696, *barnasg@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–22–079: High-End Instrumentation (HEI) Grant Program.

Date: September 26, 2023.

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: Krystyna H Szymczyk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4198, *szymczykk@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Health Services: Quality and Effectiveness Study Section.

Date: September 27–28, 2023.

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 (Virtual Meeting).

Contact Person: Angela D Thrasher, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000J, Bethesda, MD 20892, (301) 480–6894, *thrasherad@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

Date: September 27–28, 2023.

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 (Virtual Meeting).

Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Developmental Brain Disorders Study Section.

Date: September 27–29, 2023.

Time: 9:30 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 (Virtual Meeting).

Contact Person: Pat Manos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, (301) 408–9866, *manospa@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Maximizing Investigators' Research Award—F Study Section.

Date: September 27–28, 2023.

Time: 10:00 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: Brian Paul Chadwick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3586, *chadwickbp@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: August 28, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18837 Filed 8–30–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Council of Councils, September 07, 2023, Partially Closed Meeting that was published in the **Federal Register** on August 08, 2023, 88 FR 53504.

The publication is being amended to change the open session end time ''3:15 p.m.'' to ''3:00 p.m.''. In the amended portion of the notice, the open session end time of the Council of Councils meeting was listed in error. The meeting is partially closed to the public.

Dated: August 25, 2023.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18880 Filed 8–30–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 of General Medical Sciences Special Emphasis Panel; Review of K99/R00 Applications.

Date: October 24–25, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Tracy Koretsky, Ph.D., Scientific Review Officer, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3AN12F, Bethesda, Maryland

20892, 301–594–2886, *tracy.koretsky@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 24, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18833 Filed 8–30–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No USCG–2023–0392]

Recertification of Cook Inlet Regional Citizens' Advisory Council

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: The Coast Guard announces the recertification of the Cook Inlet Regional Citizens' Advisory Council (CIRCAC) as an alternative voluntary advisory group for Cook Inlet, Alaska. This certification allows the CIRCAC to monitor the activities of terminal facilities and crude oil tankers under the Cook Inlet Program established by the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990.

DATES: This recertification is effective for the period from September 01, 2023 through August 31, 2024.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email LT Case Kuikhoven, Seventeenth Coast Guard District (dpi), by phone at (907) 463–2809 or email at *case.a.kuikhoven@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

The Coast Guard published guidelines on December 31, 1992 (57 FR 62600), to assist groups seeking recertification under the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (33 U.S.C. 2732) (the Act). The Coast Guard issued a policy statement on July 7, 1993 (58 FR 36504), to clarify the factors that the Coast Guard would be considering in making its determination as to whether advisory groups should be certified in accordance with the Act, and the procedures which the Coast Guard would follow in meeting its certification responsibilities under the Act. Most recently, on September 16, 2002 (67 FR 58440), the Coast Guard changed its policy on recertification procedures for regional citizen's advisory council by requiring applicants to provide comprehensive information every three years. For each of the two years between the triennial application procedures, applicants submit a letter requesting recertification that includes a description of any substantive changes to the information provided at the previous triennial recertification. Further, public comment is only solicited during the triennial comprehensive review.

Discussion of Comments

On June 20, 2023, the Coast Guard published a Notice; Request for comments titled ''Application for Recertification of Cook Inlet Regional Citizens' Advisory Council'' in the **Federal Register** (88 FR 39857). We received 33 comments, all in support of CIRCAC's recertification. No public meeting was requested. The comments consistently cited CIRCAC's collaborative partnerships in furthering the respective communities' interest to promote safety, efforts to keep the public informed, oil spill industry monitoring efforts, effective prevention and response efforts regarding oil pollution, and to protect the sensitive marine environment along Alaska's coastline.

Recertification

By letter dated August 23, 2023, the Commander, Seventeenth Coast Guard District, certified that the CIRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification terminates on August 31, 2024.

Dated: August 23, 2023.

M. M. Dean,

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

[FR Doc. 2023–18877 Filed 8–30–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Secret Service

[Docket Number DHS–2023–0017]

Agency Information Collection Activities: Generic Information Collection: USSS Customer Satisfaction Surveys

AGENCY: Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments.

SUMMARY: The Department of Homeland Security will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. DHS previously published this ICR in the **Federal Register** on Thursday, June 8, 2023 for a 60-day public comment period. There were no comments received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted until October 30, 2023. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: You may submit comments, identified by docket number Docket #DHS–2023–0017, at:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number Docket #DHS–2023–0017. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

SUPPLEMENTARY INFORMATION: Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that our programs are effective and meet our customers' needs, the Department of Homeland Security (hereafter ''the Agency'') seeks to obtain OMB approval of a generic clearance to collect qualitative feedback on our service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs. This feedback will provide insights into customer or stakeholder 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 and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. Improving agency programs requires ongoing assessment of service delivery, by which we mean systematic review of the operation of a program compared to a set of explicit or implicit standards, as a means of contributing to the continuous improvement of the program.

The Agency will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current services and make improvements in service delivery based on feedback. The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable. The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if released, procedures outlined in Question 16 will be followed);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions 1;
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study;
- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; and
- With the exception of information needed to provide renumeration for participants of focus groups and cognitive laboratory studies, personally identifiable information (PII) is collected only to the extent necessary and is not retained.

If these conditions are not met, the Agency will submit an information collection request to OMB for approval through the normal PRA process. To obtain approval for a collection that meets the conditions of this generic clearance, a standardized form will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the comment card). The submission will have automatic approval, unless OMB identifies issues within 5 business days. The types of collections that this generic clearance covers include, but are not limited to:

- Customer comment cards/complaint forms
- Small discussion groups
- Focus Groups of customers, potential customers, delivery partners, or other stakeholders
- Cognitive laboratory studies, such as those used to refine questions or assess usability of a website
- Qualitative customer satisfaction surveys (*e.g.,* post-transaction surveys; opt-out web surveys)
- In-person observation testing (*e.g.,* website or software usability tests)

The Agency has established a manager/managing entity to serve for this generic clearance and will conduct an independent review of each information collection to ensure compliance with the terms of this clearance prior to submitting each collection to OMB. If appropriate, agencies will collect information electronically and/or use online collaboration tools to reduce burden.

Small business or other small entities may be involved in these efforts but the Agency will minimize the burden on them of information collections approved under this clearance by sampling, asking for readily available information, and using short, easy-to-complete information collection instruments. Without these types of feedback, the Agency will not have timely information to adjust its services to meet customer needs. If a confidentiality pledge is deemed useful and feasible, the Agency will only include a pledge of confidentiality that is supported by authority established in statute or regulation, that is supported by disclosure and data security policies that are consistent with the pledge, and that does not unnecessarily impede sharing of data with other agencies for compatible confidential use. If the agency includes a pledge of confidentiality, it will include a citation for the statute or regulation supporting the pledge. This is a new collection.

The Office of Management and Budget is particularly interested in comments which:

1. 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;

2. 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;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

Analysis

Agency: Department of Homeland Security (DHS)/United States Secret Service (USSS).

Title: Generic Information Collection: USSS Customer Satisfaction Surveys.

OMB Number: 1620–NEW.

Frequency: On occasion.

Affected Public: Stakeholders/participants who engage with USSS programs, investigations, and inspections; including, individuals/households and Federal, State, and Local governments.

Number of Respondents: 160,000.

Estimated Time per Respondent: 2 Minutes.

Total Burden Hours: 5,333 Hours.

Frances Humphrey,

Information Technology Program Manager, Office of the Chief information Officer.

[FR Doc. 2023–18829 Filed 8–30–23; 8:45 am]

BILLING CODE 9110–18–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7065–N–02]

60-Day Notice of Proposed Information Collection: Build America Buy America Waiver Form, OMB Control No.: 2511–0002

AGENCY: Office of the Chief Financial Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 30, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and should be sent to: Colette Pollard for a copy of the proposed forms or other available information, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone 202–402–5534 (this is not a toll-free number) or email: *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email; *Colette.Pollard@hud.gov* or telephone 202–402–0306. This is not a toll-free number.

HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Build America Buy America Waiver Form.

OMB Approval Number: 2511–0002.

Type of Request: New Collection.

Description of the need for the information and proposed use: The Department of Housing and Urban Development (HUD) requests a 6-month PRA Emergency approval pursuant to the Build America, Buy America (BABA) Act, whereby HUD may waiver grantees' application of a Buy America preference due to public interest, nonavailability, or unreasonable cost.

Respondents: Federal Government; State, Local, or Tribal Government.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD—27054e	5,000.00	1.00	5,000.00	1.00	5,000.00	$0.00	$0.00
Total					5,000.00	0.00	0.00

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35

Daniel Ballard,

Acting Deputy Chief Financial Officer.

[FR Doc. 2023–18778 Filed 8–30–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6401–N–02]

Fair Market Rents for the Housing Choice Voucher Program, Moderate Rehabilitation Single Room Occupancy Program, and Other Programs; Fiscal Year 2024

AGENCY: Office of the Assistant Secretary for Policy Development and Research, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice of fiscal year (FY) 2024 Fair Market Rents (FMRs).

SUMMARY: Section 8(c)(1) of the United States Housing Act of 1937 (USHA), as amended by the Housing Opportunities Through Modernization Act of 2016 (HOTMA), requires the Secretary to publish FMRs not less than annually, adjusted to be effective on October 1 of each year. This notice describes the methods used to calculate the FY 2024 FMRs and enumerates the procedures for Public Housing Agencies (PHAs) and other interested parties to request reevaluations of their FMRs as required by HOTMA.

DATES:

Comment Due Date: October 2, 2023.

Effective Date of Revised FMRs: October 1, 2024, unless HUD receives a valid request for reevaluation of specific area FMRs as described below.

ADDRESSES: HUD invites interested persons to submit comments regarding the FMRs and to request reevaluation of the FY 2024 FMRs. Communications must refer to the above docket number and title and should contain the information specified in the ''Request for Public Comments and FMR

Reevaluations'' section. There are two methods for submitting public comments:

1. Electronic Submission of Comments. Interested persons may submit comments or reevaluation requests electronically through the Federal eRulemaking Portal at *https://www.regulations.gov.* HUD strongly encourages commenters to submit comments or reevaluation requests electronically. Electronic submission of comments or reevaluation requests allows the author maximum time to prepare and submit a comment or reevaluation request, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments or reevaluation requests submitted electronically through the *https://www.regulations.gov* website can be viewed by other submitters and interested members of the public. Commenters or reevaluation requestors should follow instructions provided on that site to submit comments or reevaluation requests electronically.

2. Submission of Comments by Mail. Members of the public may submit comments or requests for reevaluation by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at all Federal agencies, however, submission of comments by standard mail often results in delayed delivery. To ensure timely receipt of comments or reevaluation requests, HUD recommends that comments or requests submitted by standard mail be submitted at least two weeks in advance of the deadline. HUD will make comments or reevaluation requests received by mail available to the public at *https://www.regulations.gov.*

Note: To receive consideration as public comments or reevaluation requests, comments or requests must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimile Comments or Reevaluation Requests. HUD does not accept facsimile (FAX) comments or requests for FMR reevaluation.

FOR FURTHER INFORMATION CONTACT: For technical information on the methodology used to develop FMRs or a listing of all FMRs, please call the HUD USER information line at 800–245–2691 or access the information on the HUD USER website at *https://www.huduser.gov/portal/datasets/fmr.html.*

Questions related to the use of FMRs or voucher payment standards should be directed to the respective local HUD program staff or the Office of Public and Indian Housing Customer Service Center at *https://www.hud.gov/program_offices/public_indian_housing/about/css.* Questions on how to conduct FMR surveys may be addressed to the electronic mailbox for the Program Parameters and Research Division at *pprd@hud.gov.*

Electronic Data Availability. This **Federal Register** notice will be available electronically from the HUD User page at *https://www.huduser.gov/portal/datasets/fmr.html.* **Federal Register** notices also are available electronically from *https://www.federalregister.gov/,* the U.S. Government Printing Office website. Complete documentation of the methods and data used to compute each area's FY 2024 FMRs is available at *https://www.huduser.gov/portal/datasets/fmr.html#2024_query.* FY 2024 FMRs are available in a variety of electronic formats at *https://www.huduser.gov/portal/datasets/fmr.html,* including in PDF and Microsoft Excel. Small Area FMRs for all metropolitan FMR areas are available in Microsoft Excel format at: *https://www.huduser.gov/portal/datasets/fmr/smallarea/index.html.* For informational purposes, HUD also publishes 50th percentile rents for all FMR areas at *https://www.huduser.gov/portal/datasets/50per.html.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 8 of the USHA (42 U.S.C. 1437f) authorizes housing assistance to aid lower-income families in renting safe and decent housing. Housing assistance payments are limited by FMRs established by HUD for different geographic areas. In the Housing Choice Voucher (HCV) program, the FMR is the basis for determining the ''payment standard amount'' used to calculate the maximum monthly subsidy for an assisted family. See 24 CFR 982.503. HUD also uses the FMRs to determine initial renewal rents for some expiring project-based Section 8 contracts, initial rents for housing assistance payment contracts in the Moderate Rehabilitation Single Room Occupancy program, rent ceilings for rental units in both the HOME Investment Partnerships program and the Emergency Solution Grants program, calculation of maximum award amounts for Continuum of Care recipients and the maximum amount of rent a recipient may pay for property leased with Continuum of Care funds, and calculation of flat rents in Public Housing units. In general, the FMR for an area is the amount that a tenant would need to pay the gross rent (shelter rent plus utilities) of privately owned, decent, and safe rental housing of a modest (non-luxury) nature with suitable amenities. The FMR is also used to determine the Performance Based Contract Administration Fee in Multifamily Housing. HUD's FMR calculations represent HUD's best effort to estimate the 40th percentile gross rent [1] paid by recent movers into standard quality units in each FMR area. In addition, all rents subsidized under the HCV program must meet reasonable rent standards.

On June 23, 2023, HUD published a notice of Proposed Changes to the Methodology Used for Calculating Fair Market Rents.[2] For FY 2024 FMRs, HUD is implementing the proposed changes described in that notice. The first affects how HUD determines the ''recent mover adjustment factor'' to meet its regulatory objective of setting the FMR from the distribution of rental units occupied by recent movers. The second change affects how HUD inflates the recent mover rent to the most recent full calendar year using a Gross Rent Inflation Adjustment Factor. The methodology used in each of these steps is described in more detail in the following section.

II. Procedures for the Development of FMRs

Section 8(c)(1) of the USHA,[3] as amended by HOTMA (Pub. L. 114–201, enacted July 29, 2016), requires the Secretary of HUD to publish FMRs not less than annually. Section 8(c)(1)(A) states that each FMR ''shall be adjusted to be effective on October 1 of each year to reflect changes, based on the most recent available data trended so the rentals will be current for the year to which they apply. . . .'' Section 8(c)(1)(B) requires that HUD publish, not less than annually, new FMRs on the World Wide Web or in any other manner specified by the Secretary, and that HUD must also notify the public of when it publishes FMRs by **Federal Register** notice. After notification, the FMRs ''shall become effective no earlier than 30 days after the date of such publication,'' and HUD must provide a procedure for the public to comment and request a reevaluation of the FMRs in a jurisdiction before the FMRs

[1] HUD also calculates and posts 50th percentile rent estimates for the purposes of Success Rate Payment Standards as defined at 24 CFR 982.503(e) (estimates available at: *https://www.huduser.gov/portal/datasets/50per.html*).

[2] 88 FR 41118.

[3] 42 U.S.C. 1437f.

become effective. Consistent with the statute, HUD is issuing this notice to notify the public that FY 2024 FMRs are available at *https://www.huduser.gov/portal/datasets/fmr.html* and will become effective on October 1, 2023. This notice also provides procedures for FMR reevaluation requests.

III. FMR Methodology

This section provides a brief overview of how HUD computes the FY 2024 FMRs.

For complete information on how HUD derives each area's FMRs, see the online documentation at *https://www.huduser.gov/portal/datasets/fmr.html#2024_query*.

A. Geographic Area Definitions

The FY 2024 FMRs are based on the updated metropolitan area definitions published by the Office of Management and Budget (OMB) on September 14, 2018 and first incorporated by the Census Bureau into the 2019 American Community Survey (ACS) data, and the corresponding FY 2022 FMRs. On July 21, 2023, OMB published Bulletin No. 23–01 which contains revisions to metropolitan area definitions. However, the Census Bureau has not yet incorporated these revisions into the data available to HUD, and therefore HUD is not using these new definitions for FY 2024.

B. Base Year Rents

For FY 2024 FMRs, HUD uses the U.S. Census Bureau's 5-year ACS data collected between 2017 and 2021 as the ''base rents'' for the FMR calculations. These data are the most current ACS data available at the time that HUD calculates the FY 2024 FMRs. HUD pairs a ''margin of error'' test [4] with an additional requirement based on the number of survey observations supporting the estimate to improve the statistical reliability of the ACS data used in the FMR calculations. The Census Bureau does not provide HUD with an exact count of the number of observations supporting the ACS estimate; rather, the Bureau provides HUD with categories of the number of survey responses underlying the estimate, including whether the estimate is based on more than 100 observations. Using these categories, HUD requires that, in addition to meeting the ''margin of error'' test, ACS rent estimates must be based on at least 100 observations to be used as base rents.

For areas in which the 5-year ACS data for two-bedroom, standard quality gross rents do not pass the statistical reliability tests (*i.e.,* have a margin of error ratio greater than 50 percent or fewer than 100 observations), HUD will use an average of the base rents over the three most recent years [5] (provided that there is data available for at least two of these years),[6] or if such data are not available, using the two-bedroom rent data within the next largest geographic area. For a metropolitan subarea, the next largest area is its containing metropolitan area. For a non-metropolitan area, the next largest area is the State non-metropolitan portion.

C. Recent-Mover Factors

Following the assignment of the standard quality two-bedroom rent described above, HUD applies a recent-mover factor to these rents. HUD calculates the recent-mover factor as the change between the 5-year 2017–2021 standard quality two-bedroom gross rent and the 1-year 2021 recent mover gross rent for the recent mover factor area. HUD does not allow recent-mover factors to lower the standard quality base rent; therefore, if the 5-year standard quality rent is larger than the comparable 1-year recent mover rent, HUD sets the recent-mover factor to 1. When the recent-mover factor is greater than one and calculated for the same geographic area as the base rent, HUD is, in effect, replacing the base rent with the recent-mover rent for that area.

Newly for FY 2024, HUD is modifying the definition of ''recent mover'' used in determining the 2021 recent mover gross rent as described above. To make its recent mover adjustment as reflective of current market conditions as possible, HUD first considers the rents of households who moved into their unit only in the current ACS year. For ACS 2021, this means that the maximum length of time for a household to have lived in its current unit and still be considered a recent mover under this definition would be 11 months. This differs from HUD's prior practice of considering rents from householders who moved into their unit in either the current year or prior year.

However, restricting the ACS universe to recent movers limits the sample size supporting the resulting estimates, potentially harming the statistical reliability of those estimates. HUD applies the same two statistical reliability checks to each ACS recent mover estimate as it does for the base rent estimate. First, the estimate must be supported by at least 100 sample cases from the ACS. Second, the estimate must have a margin of error that is smaller than half the estimate itself. These criteria also apply for the new, single-year definition of recent movers. For areas without an ACS estimate meeting these criteria, HUD next checks the estimate tabulated from two-year recent movers, following its prior methodology.

D. Other Rent Survey Data

HUD calculates base rents for the insular areas using data collected during the 2010 decennial census of American Samoa, the Northern Mariana Islands, and the Virgin Islands beginning with the FY 2016 FMRs.[7] HUD updates the 2010 base year data to 2021 using the growth in national ACS data for the FY 2024 FMRs. Note that while the 2010 decennial census also included Guam, HUD uses the result of a more recent rent survey in calculating the FMRs for Guam, as discussed in the following paragraph. HUD is working with the Census Bureau to provide special tabulations of the 2020 Island Area Census and hopes to include these data in FY 2025 FMRs.

HUD does not use ACS data to establish the base rent or recent-mover factor in cases where it has locally collected survey data which are more recent than the 2021 ACS. For larger metropolitan areas that have valid ACS one-year recent-mover data, survey data may not be any older than the mid-point of the calendar year for the ACS one-year data. Since the ACS one-year data used for the FY 2024 FMRs is from 2021, larger areas with valid one-year recent mover data may not use other survey data collected before June 30, 2021 for the FY 2024 FMRs. Areas without statistically reliable 1-year ACS data may continue to use local survey data until the mid-point of the 5-year ACS data is more recent than the local survey. For FY 2024 FMRs, the following are Metropolitan Statistical Areas (MSAs), HUD Metro FMR Areas, or non-metropolitan counties that have FMRs based on local ad hoc surveys:

[4] HUD's margin of error test requires that the margin of error of the ACS estimate is less than half the size of the estimate itself.

[5] For FY 2024, the three years of ACS data in question are 2018, 2019 and 2020. HUD adjusts the 2018 and 2019 data to be denominated in 2020 dollars using the growth in Consumer Price Index (CPI)-based gross rents measured between 2018 and 2020.

[6] To be used in the three-year average calculation, the 5-year estimates must be minimally statistically qualified; that is, the margin of error of the estimates must be less than half the size of the estimate.

[7] The ACS is not conducted in the Pacific Islands (Guam, Northern Mariana Islands and American Samoa) or the US Virgin Islands. As part of the 2010 Decennial Census, the Census Bureau conducted ''long-form'' sample surveys for these areas. HUD uses the results gathered by this long form survey for the FY 2024 FMRs.

- HUD uses survey data from 2019 to calculate the FMRs for Kauai County, HI; and Guam.
- HUD uses survey data from 2021 to calculate the FMRs for Abilene, TX MSA; Asheville, NC HUD Metro FMR Area; Boston-Cambridge-Quincy, MA-NH HUD Metro FMR Area; Bremerton-Silverdale, WA MSA; Iron County, UT; Knox County, ME; Lincoln County, ME; New York, NY HUD Metro FMR Area; Portland, ME HUD Metro FMR Area; Portland-Vancouver-Hillsboro, OR-WA MSA; San Diego-Carlsbad, CA MSA; Santa Maria-Santa Barbara, CA MSA; Transylvania County, NC; and Waldo County, ME.
- HUD uses survey data from 2022 to calculate the FMRs for Grand Rapids-Wyoming, MI HUD Metro FMR Area; Hawaii County, HI; Hood River County, OR; Salinas, CA MSA; Seattle-Bellevue, WA HUD Metro FMR Area; and Wasco County, OR.
- HUD uses survey data from 2023 to calculate the FMRs for San Benito County, CA HUD Metro FMR Area; and Santa Cruz-Watsonville, CA MSA.

E. Gross Rent Inflation Adjustment Factors

The ACS recent mover rent estimates as described above produce a rent value that is ''as of'' 2021. In the past, HUD has updated the latest ACS-based rent estimates with one year of gross rent inflation measured with the 23 local or 4 regional CPI components rent of primary residence and household fuels and utilities depending on the location of the FMR area. For FY 2023, HUD augmented the CPI methodology by including available private data sources along with CPI data in calculating a weighted average gross rent inflation factor that was used to update the ACS-based ''as of'' 2020 rent through 2021. HUD applied a weight of 60 percent to the average of the change in private data sources and 40 percent to the annual change in CPI gross rents. In places without sufficient private rent data sources, the actual inflation adjustment process solely used regional CPI data.

For FY 2024, HUD is continuing to augment CPI rent inflation data with private sources of rent data to create a gross rent inflation adjustment factor. Recent research has indicated that there is a substantial lag in the overall CPI rent of primary residence index's ability to capture changes in recent mover rents, and that private rent measure are often better at capturing such changes quickly. The private measures of rent used by HUD are the RealPage average effective rent per unit, Moody's Analytics REIS average market rent, CoStar Group average effective rent, CoreLogic, Inc. single-family combined 3-bedroom median rent, ApartmentList Rent Estimate, and Zillow Observed Rent Index.

In calculating a measure of inflation from these data, HUD first takes the annual average of each statistic, then its year-to-year change. HUD then takes the mean of changes from all available sources for each area. Next, HUD takes an average of this private-sector measure of rent inflation with rent inflation as captured by the CPI for the area, where the private-sector measure is weighted at approximately 55.8 percent and the CPI rent inflation measure is weighted at approximately 44.2 percent. HUD has determined these weights by comparing the national average of the private rent changes and changes in CPI rent of primary residence to changes in the national average of recent mover rents from the ACS from 2017 through 2021. HUD weights the private data averages and overall CPI rent of primary residence in such a way as to minimize the root mean squared error between the resulting average and the ACS recent mover rents. For future FMRs, HUD will update the weights by adding the most recent years of ACS recent mover rents, private rent data, and CPI rent of primary residence to the analysis.

HUD uses a local measure of private rent inflation for markets that are covered by at least three of the six available sources of private rent data. HUD combines this local measure of rent inflation with either the local metropolitan area CPI rent of primary residence for the 23 areas where such data exist, or the regional CPI rent in areas without a local index.

Unlike in FY 2023, for areas without at least three of the six private rent data sources available, HUD uses a regional average of private rent inflation factors alongside the regional CPI rent of primary residence using the nationally derived weights described above. HUD constructs the regional average by taking the rental unit weighted average of the change in rents of each area in a region that does have private rent data coverage. This ensures that smaller areas which are not covered by the private sources directly still have current rental market conditions taken into account in the calculation of the rent inflation factor for such areas.

Finally, HUD averages the result of this step with the year-to-year change in the CPI housing fuels and utilities index for the area in order to make the resulting inflation measure reflective of gross rents. The results of this step are gross rent estimates that are ''as of'' 2022.

F. Trend Factor Forecasts

Following the application of the appropriate gross rent inflation factor, HUD trends the gross rent estimate from 2022 to FY 2024 using a trend factor which is based on local or regional forecasts of CPI gross rent data. HUD derived a trend factor for each Class A CPI area and Class B/C CPI region using time series models based on national inputs (National Input Model or NIM), local inputs (Local Input Model or LIM) and historical values of the predicted series (Pure Time Series—PTS). HUD chose the actual model used for each CPI area's trend factor based on which model generates the lowest Root Mean Square Error (RMSE) statistic and applied the trend factors to the corresponding FMR areas. HUD established the type of model for each forecast (NIM, LIM, or PTS) for the FY 2020 FMRs and is keeping it constant for 5 years. HUD will reassess the model selections during the calculation of the FY 2025 FMRs. More details on the trend factor forecasts are available in the June 5, 2019, **Federal Register** notice (84 FR 26141) and are available at *https://www.federalregister.gov/documents/2019/06/05/2019-11763/proposed-changes-to-the-methodology-used-for-estimating-fair-market-rents.*

G. Bedroom Rent Adjustments

HUD updates the bedroom ratios used in the calculation of FMRs annually. The bedroom ratios HUD uses in the calculation of FY 2024 FMRs are calculated from three, five-year ACS data series (2015–2019, 2016–2020, and 2017–2021). HUD only uses estimates with a margin of error ratio of less than 50 percent. If an area does not have reliable estimates in at least two of the previous three ACS releases, HUD uses the bedroom ratios for the area's larger parent geography.

HUD uses two-bedroom units for its primary calculation of FMR estimates. This is generally the most common size of rental unit and, therefore, the most reliable to survey and analyze. After estimating two-bedroom FMRs, HUD calculates bedroom ratios for each FMR area which relate the prices of smaller and larger units to the cost of two-bedroom units. To ensure an adequate distributional fit in these bedroom ratio calculations for individual FMR areas, HUD establishes bedroom interval ranges which set upper and lower limits for bedroom ratios nationwide, based on an analysis of the range of such intervals for all areas with large enough samples to permit accurate bedroom ratio determinations.

In the calculation of FY 2024 FMR estimates, HUD sets the bedroom interval ranges as follows: efficiency FMRs are constrained to fall between 0.68 and 0.87 of the two-bedroom FMR; one-bedroom FMRs must be between 0.76 and 0.89 of the two-bedroom FMR; three-bedroom FMRs (prior to the adjustments described below) must be between 1.12 and 1.30 of the two-bedroom FMR; and four-bedroom FMRs (again, prior to adjustment) must be between 1.24 and 1.58 of the two-bedroom FMR. Given that these interval ranges partially overlap across unit bedroom counts, HUD further adjusts bedroom ratios for a given FMR area, if necessary, to ensure that higher bedroom-count units have higher rents than lower bedroom-count units within that area.

HUD also further adjusts the rents for three-bedroom and larger units to reflect HUD's policy to set higher rents for these units.[8] This adjustment is intended to increase the likelihood that the largest families, who have the most difficulty in leasing units, will be successful in finding eligible program units. The adjustment adds 8.7 percent to the unadjusted three-bedroom FMR estimates and adds 7.7 percent to the unadjusted four-bedroom FMR estimates.

HUD derives FMRs for units with more than four bedrooms by adding 15 percent to the four-bedroom FMR for each extra bedroom. For example, the FMR for a five-bedroom unit is 1.15 times the four-bedroom FMR, and the FMR for a six-bedroom unit is 1.30 times the four-bedroom FMR. Similarly, HUD derives FMRs for single-room occupancy units by subtracting 25 percent from the zero-bedroom FMR (*i.e.,* they are set at 0.75 times the zero-bedroom (efficiency) FMR).[9]

H. Minimum FMRs

All FMRs are subject to a minimum rent based on State or national non-metropolitan area median rent. HUD calculates a population-weighted median two-bedroom FMR across all non-metropolitan counties or county-equivalents of each State, which, for the purposes of FMRs, is the State minimum rent. State-minimum rents for each FMR area are available in the FY 2024 FMR Documentation System, available at *https://www.huduser.gov/portal/datasets/fmr.html#2024_query.* HUD also calculates the population weighted median FMR rent across all non-metropolitan areas of the country, which, for the purposes of FMRs, is the national non-metropolitan rent. For FY 2024, the national non-metropolitan rent is $905. The applicable minimum rent for a particular area is the *lower* of the State or national non-metropolitan median. Each area's two-bedroom FMR must be no less than the applicable minimum rent.

I. Limit on FMR Decreases

Within the Small Area FMR final rule published on November 16, 2016,[10] HUD amended 24 CFR 888.113 to include a limit on the amount that FMRs may annually decrease. The current year's FMRs resulting from the application of the bedroom ratios, as discussed in section (E) above, may be no less than 90 percent of the prior year's FMRs for units with the same number of bedrooms. Accordingly, if the current year's FMRs are less than 90 percent of the prior year's FMRs as calculated by the above methodology, HUD sets the current year's FMRs equal to 90 percent of the prior year's FMRs. For areas where use of Small Area FMRs in the administration of their voucher programs is required, the FY 2024 Small Area FMRs may be no less than 90 percent of the FY 2023 Small Area FMRs. For all other metropolitan areas, the FY 2024 Small Area FMRs may be no less than 90 percent of the greater of the FY 2023 metropolitan area wide FMRs or the applicable FY 2023 Small Area FMR.

PHAs operating in areas where the calculated FMR is lower than the published FMR (*i.e.,* those areas where HUD has limited the decrease in the annual change in the FMR to 10 percent) may request payment standards below the basic range (24 CFR 982.503(d)) and reference the ''unfloored'' rents (*i.e.,* the unfinalized FMRs calculated by HUD prior to application of the 10-percent-decrease limit) depicted in the FY 2024 FMR Documentation System (available at: *https://www.huduser.gov/portal/datasets/fmr.html#2024_query*).

J. Methodology Appendix

To derive the weights used for the private shelter rent inflation factors and the CPI rent of primary residence, HUD compared the national average private rent inflation rates and CPI rent of primary residence inflation rates to the national average increase in ACS recent mover rents. While private rent data and ACS recent mover rents measure rent inflation for recent movers, the CPI rent of primary residence measures rent inflation across all rental units, and while ACS recent mover rents and CPI rent of primary residence originate from representative samples, private rent data inflation is derived from large samples of rents that are not constructed to be fully representative of the rental stock. To temper any potential bias arising from the non-representativeness of the private data sources, HUD constructs a weighted average of private rent data and CPI rent of primary residence that minimizes the root mean squared error between the weighted average changes in private rent data and CPI rent of primary residence compared to the changes in national average ACS recent mover rents for the years 2017 through 2021. Since 2020 ACS recent mover rent data are not available, HUD interpolates a value for 2020 by assuming the rate of increase was constant from 2019 to 2021. The resulting weights are approximately 55.8 percent private rent data and 44.2 percent CPI rent of primary residence.

	2017–18	2018–19	2019–20	2020–21	Weights
Average Private Change	3.34%	3.62%	1.11%	7.59%	Private—0.558388.
ACS National Recent Mover Change	5.24%	4.06%	7.34%	7.34%	CPI RPR—0.441612.
CPI RPR	3.62%	3.71%	3.12%	2.25%	
Weighted Avg of CPI RPR and Private Change	3.46%	3.66%	2.00%	5.23%	
Squared Error	3E–04	2E–05	3E–03	4E–04	
Minimum Possible RMSE	3.01%				

[8] As mentioned above, HUD applies the interval ranges for the three-bedroom and four-bedroom FMR ratios prior to making these adjustments. In other words, the adjusted three- and four-bedroom FMRs can exceed the interval ranges but the unadjusted FMRs cannot.

[9] As established in the interim rules implementing the provisions of the Quality Housing and Work Responsibility Act of 1998 (Title V of the FY 1999 HUD Appropriations Act; Pub. L. 105–276) in 24 CFR 982.604.

[10] 81 FR 80567.

HUD will use these values of the weights for the FY 2024 FMRs and will perform the same analysis including new data for purposes of setting weights each year, *e.g.,* for FY2025 FMRs, 2022 ACS recent mover rents, 2022 private rent data and 2022 CPI rent of primary residence would be included in the analysis to set the weights. Thus, the weights for private rent data and CPI rent of primary residence in the gross rent inflation adjustment factors will vary based on such reanalysis in future versions of FMRs.

IV. Small Area FMRs

HUD lists Small Area FMRs for all metropolitan areas in the Small Area FMR Schedule. Metropolitan PHAs operating in areas where the use of Small Area FMRs is not mandated should contact their local HUD field office to request approval for using Small Area FMRs in the operation of their Housing Choice Voucher program.

HUD calculates Small Area FMRs directly from the standard quality gross rents provided to HUD by the Census Bureau for ZIP Code Tabulation Areas (ZCTAs) when such data are statistically reliable. The ZCTA two-bedroom equivalent 40th percentile gross rent is analogous to the standard quality base rents set for metropolitan areas and non-metropolitan counties. For each ZCTA with statistically reliable gross rent estimates, using the expanded test of statistical reliability first used in FY 2018 (*i.e.,* estimates with margins of error ratios below 50 percent and based on at least 100 observations), HUD calculates a two-bedroom equivalent 40th percentile gross rent using the first statistically reliable gross rent distribution data from the following data sets (in this order): two-bedroom gross rents, one-bedroom gross rents, and three-bedroom gross rents. If either the one-bedroom or three-bedroom gross rent data are used because the two-bedroom gross rent data are not statistically reliable, HUD converts the one-bedroom or three-bedroom 40th percentile gross rent to a two-bedroom equivalent rent using the bedroom ratios for the ZCTA's parent metropolitan area. To increase stability to these Small Area FMR estimates, HUD averages the latest three years of gross rent estimates.[11]

For ZCTAs without usable gross rent data by bedroom count, HUD calculates Small Area FMRs using the rent ratio method. To calculate Small Area FMRs using a rent ratio, HUD divides the median gross rent across all bedrooms for the ZCTA by the similar median gross rent for the metropolitan area of the ZCTA. If a ZCTA does not have reliable rent data at the all-bedroom level, HUD will then check to see if the ZCTA borders other ZCTAs that themselves have reliable rent data. If at least half of a ZCTA's ''neighbors'' have such data, HUD will use the weighted average of those estimates as the basis for the Small Area FMR rather than a county proxy, where the weight is the length of the shared boundary between the ZCTA and its neighbor. In small areas where the neighboring ZCTA median gross rents are not statistically reliable, HUD substitutes the median gross rent for the county containing the ZIP code in the numerator of the rent ratio calculation. HUD multiplies this rent ratio by the current two-bedroom FMR for the metropolitan area containing the small area to generate the current year two-bedroom FMR for the small area.

HUD continues to use a rolling average of ACS data in calculating the Small Area FMR rent ratios. HUD believes coupling the most current data with previous year's data minimizes excessive year-to-year variability in Small Area FMR rent ratios due to sampling variance. Therefore, for FY 2024 Small Area FMRs, HUD has updated the rent ratios to use an average of the rent ratios calculated from the 2015–2019, 2016–2020, and 2017–2021 5-year ACS estimates.

HUD limits each two-bedroom Small Area FMR to be no more than 150 percent of the two-bedroom FMR for the metropolitan area where the ZIP code is located.

V. Response to Comments on Proposed Changes to FMR Calculation

On June 23, 2023, HUD published a notice of Proposed Changes to the Methodology Used for Calculating Fair Market Rents.[12] In response to this notice HUD received 25 public comments. The following sections respond to these comments.

a. Public Comments Supporting the Proposed Changes to the Methodology Used for Calculating FMRs

The majority of commenters supported both of HUD's proposed changes to the FY 2024 FMR calculation methodology, specifically: (1) retaining and expanding the use of rent inflation factors calculated by private sector data sources and (2) changing the ''recent mover'' definition from a maximum of 23 months to 11 months. Commenters stated that these changes are likely to produce FMRs that are more accurate because the private data sources are updated more recently than the CPI and because rents for tenants who have moved within the past year are more reflective of current rental prices. Several commenters also mentioned the importance of capturing the high rate of inflation.

There were no commenters opposed to the ''recent mover'' redefinition, although one commenter expressed concern that it could increase volatility. There were also no commenters expressly opposed to the expanded use of private data, although some commenters expressed concerns about insufficient transparency into the companies' methodologies and into HUD's selection criteria.

Several commenters applauded HUD for the methodological changes implemented in FY 2023, noting that FMRs were significantly more reflective of real market conditions last year than in the past.

HUD Response: Partially in response to the supportive comments, HUD is retaining and expanding the use of private rent inflation data in its FMR calculation. HUD consistently strives for transparency in its FMR calculation by maintaining an online lookup tool that shows the component factors of each area's FMR calculation. HUD is committed to further research on the various methodologies used by private companies and making this research publicly available.

b. Public Comments Recommending Additional Changes or Alterations to the Proposed Changes to the Methodology Used for Calculating FMRs

i. Suggestions To Further Expand Usage of Private or Alternative Data Sources

While most commenters expressed support for the expanded use of private data as proposed for FY 2024, several commenters recommended that HUD expand its use even further in FY 2025. One commenter recommended that HUD replace the use of 5-year ACS data with private data since this accounts for 80% of FMR areas. Another recommended that HUD augment the gross rent CPI data used in the Trend Factor calculation with private data, (which they had also recommended in their public comment submitted for FY 2023). Another commenter recommended additional private or alternative data sources for HUD to consider including in FY 2025 calculations. Another commenter expressed concern that HUD has

[11] For example, for FY 2024 Small Area FMRs, HUD averages the gross rents from 2019, 2020, and 2021 5-Year ACS estimates. The 2019 and 2020 gross rent estimates would be adjusted to 2021 dollars using the metropolitan area's gross rent CPI adjustment factors.

[12] 88 FR 41118.

provided insufficient justification for its three private data sources standard. Another requested further clarification from HUD on HUD's selection criteria for private data sources.

ii. Request for More Transparency in Private Data

Multiple commenters expressed concern that there is insufficient transparency into the methodologies used by the private companies in calculating rental rates.

iii. Request That FMR Calculation Be More Localized

Two commenters requested that local data sources, specifically the University of Southern California Lusk Center for Real Estate, University of California Los Angeles Lewis Center for Regional Policy Studies, and the New York City Housing and Vacancy Survey (NYCHVS), be added to the private data as alternative sources. Another commenter requested that local PHAs be allowed to set their own FMRs in order to properly account for hyperlocal conditions, while another suggested that FMRs instead be set ''within the state based on local conditions.'' A commenter recommended that HUD consider basing its inflation adjustment on smaller geographic areas for rental markets with many submarkets, such as Los Angeles.

HUD Response: The private rental data available to HUD do not represent the entirety of the rental market. The data sources are in some cases based on online rental listings or consist of surveys of large multifamily properties. Research has shown that despite these limitations, the changes in rent reported by these sources are similar to the change in rent from the overall rental market. Therefore, HUD is comfortable using these sources as a source of the shelter rent inflation rate for markets where such data are available. However, they cannot be used to establish the base rent for each area, as they do not provide a 40th percentile rent statistic, and if they did, such a statistic would not be drawn from a representative sample of the entire rental market as is the case with gross rent estimates from the ACS.

HUD is aware that, given the limitations in the CPI rent of primary residence as a measure of recent mover rents, there are concerns in continuing to rely on that series in the trend factor. However, given the complexities of forecasting, HUD has not arrived an alternative methodology. Moreover, until very recently, both the overall CPI rent of primary residence and the CPI new tenant repeat rent index showed similar rates of inflation, suggesting that convergence in the future is a reasonable assumption.

As previously stated, HUD consistently strives for transparency in its FMR calculation by maintaining an online lookup tool that shows the component factors of each area's FMR calculation. HUD is committed to further research on the various methodologies used by private companies and making this research publicly available. In some cases, the proprietary nature of the data and methodologies used by various companies limit the ability of HUD to provide transparency.

With respect to alternative data sources, interested parties may submit any survey or comprehensive rental market study that provides a 40th percentile rent estimate for recent movers that is more current than the year of the ACS for consideration to HUD. In the case of the New York Housing and Vacancy Survey however, the most recent data are from 2017.

c. Public Comments That Address Alternative FMR Calculations and the Determination of FMR Amounts

i. Comments Concerning the FMR Amounts

Multiple commenters indicated that FMR values have historically been too low, and continue to be too low, causing individuals and families to be unable to find housing. On the other hand, some commenters indicated that high FMR values have negatively affected tenant ability to afford units when flat rents are set to 80% of FMRs.

ii. Comments Suggesting Alternative FMR Calculation Methodologies

Multiple commenters suggested alternative methodologies for HUD to use in calculating FMRs that differ significantly from current methods. One commenter encouraged the use of a ''Fair and Reasonable'' approach in the setting of FMR amounts, rather than the method currently used to set FMR rates. One commenter lamented that Public Housing Authorities have had difficulty serving tenants amidst rising rental prices and recommended that PHAs be allowed to determine the rental rates for their own jurisdiction based on a ''rent reasonableness'' standard, their budget, and their total number of assigned vouchers. Another commenter recommended that HUD factor vacancy rates into its FMR calculations, although they did not expand on how it should be factored in. A commenter recommended that HUD fundamentally change the FMR calculation from an estimate of current rents in the area to instead be based on ''what the near-term rent needs to be to attract the private capital necessary to create the type of housing that is desired'' in neighborhoods that ''lack affordable housing units but face strong demand from local residents.'' One commenter recommended that HUD adopt an Island-Wide FMR specifically for Puerto Rico to increase administrative efficiency. Another commenter recommended that HUD reconsider its use of 40th percentile rent limits; if voucher holders are unable to secure rental housing at this rate, the commenter suggested that PHAs have the discretion to incorporate the use of 50th percentile rent levels instead.

HUD Response: In setting the overall level of the FMR, HUD must balance the interests of ensuring that families have an adequate choice of decent and safe housing while seeking to maximize the number of families who can receive assistance. HUD's current regulations set the FMR at the 40th percentile rent, a statistic which is below the average rent in each area, to achieve this balance. With respect to the Voucher program, there are numerous ways in which the payment standard can exceed the FMR, including exception payment standards and success rate payment standards.

With respect to flat rents, there are numerous options for PHAs in circumstances where the FMR is too high for an appropriate flat rent, such as the use of Small Area FMRs or conducting a rent comparability study.

HUD periodically conducts research on potential improvements to the voucher program. For example, several PHAs who participate in the Moving to Work demonstration have conducted their own rental market studies and determined their own payment standards rather than rely on the FMR. The Department is committed to continuing to evaluate this and other research and determine the best approach to determining rental subsidy rates.

It is not clear that setting higher FMRs would increase housing supply, as the largest barrier to the creation of new affordable housing in many areas is land use restrictions. Instead, setting FMRs higher based on a desire to attract new capital would likely lead to undue subsidy capture by current landlords.

HUD is committed to working with stakeholders in Puerto Rico regarding what the appropriate level of geography is for determining Fair Market Rent areas. To date, HUD has received little feedback on this issue.

d. Public Comments Regarding Suggestions for the Methodology Used for Calculating FMRs After FY 2024

One commenter recommended that for areas that use SAFMRs, HUD replace the three private data sources standard with either a minimum population or rental unit count, as these areas may have the requisite population/unit density.

One commenter recommended that rather than using a minimum of three private data sources, HUD use only data from the two private providers—CoreLogic and Zillow—that have an established relationship with the CPI according to the BLS/Fed study. Another commenter recommended that HUD continue to follow up on the BLS/Fed study with a longitudinal study to observe the accuracy of FMR calculation methods with private sector data.

One commenter who supported both of HUD's proposals recommended that HUD increase transparency by producing a new annual report detailing national FMR statistics in the aggregate (*i.e.,* percent of areas where FMRs did not pass statistical reliability checks).

One commenter tentatively supports the use of private data, but requests that the sources be required to release their coverage areas and methodology for public comment; this commenter also tentatively supports the redefinition of ''recent mover'' but is concerned that it may increase volatility and suggests that HUD incorporate additional safeguards in general against year-over-year volatility.

HUD Response: With respect to the use of only CoreLogic and Zillow, note that the BLS/Fed study did not examine the other data sources available to HUD. HUD has replicated the correlations among the additional sources and the CPI NTRR as was done in the study and feels that the results justify including the additional sources. Additionally, the BLS/Fed study considered only national changes in rent. At the local level, rent data are more volatile and including additional data sources reduces some of this volatility. HUD does intend to continue tracking the relationship among private sources of rent data and the CPI NTRR subject to the latter's availability.

With respect to transparency, HUD would be willing to provide aggregate statistics on the various adjustment categories that FMR areas are subject to; however, with many such adjustments it is not clear which would be most salient for users. Interested parties are invited to comment on this in response to this notice.

On the issue of geographic coverage, HUD only uses private sources in cases where the geographic coverage closely matches HUD's FMR area definitions.

HUD agrees that volatility is a concern in setting FMRs and making methodology changes. At the same time, rental markets themselves may be genuinely volatile and therefore FMRs may exhibit some degree of volatility by virtue of being accurately calculated.

VI. Request for Public Comments and FMR Reevaluations

HUD accepts public comments on the methods HUD uses to calculate FY 2024 FMRs and requests for reevaluation of FMRs for specific areas for 30 days after the publication of this notice. HUD lacks the resources to conduct local surveys of rents to address comments filed regarding the FMR levels for specific areas. PHAs may continue to fund such surveys independently, as specified below, using ongoing administrative fees or their administrative fee reserve if they so choose. HUD continually strives to calculate FMRs that meet the statutory requirement of using ''the most recent available data'' while also serving as an effective program parameter.

FMR Reevaluations

42 U.S.C. 1437f(c)(1)(B) includes the following: ''The Secretary shall establish a procedure for public housing agencies and other interested parties to comment on such fair market rentals and to request, within a time specified by the Secretary, reevaluation of the fair market rentals in a jurisdiction before such rentals become effective.''

PHAs or other parties interested in requesting HUD's reevaluation of their area's FY 2024 FMRs, as provided for under section 8(c)(1)(B) of USHA, must follow the following procedures:

1. By the end of the 30-day comment period, PHAs or other parties must submit reevaluation requests through *https://www.regulations.gov/* or directly to HUD as described in the Addresses section above. The area's PHA or, in multi-jurisdictional areas, PHA(s) representing at least half of the voucher tenants in the FMR area, must agree that the reevaluation is necessary.

2. The requestor(s) must supply HUD with data more recent than the 2021 ACS data used in the calculation of the FY 2024 FMRs. HUD requires data on gross rents paid in the FMR area for occupied standard quality rental housing units. Occupied recent mover units (defined as those who moved in the past 24 months, although a shorter definition may also be used at the requestors discretion) provide the best data. The data delivered must be sufficient for HUD to calculate a 40th and 50th percentile two-bedroom gross rent.[13] Should this type of data not be available, requestors may gather this information using the survey guidance available at *https://www.huduser.gov/portal/datasets/fmr/NoteRevisedAreaSurveyProcedures.pdf* and *https://www.huduser.gov/portal/datasets/fmr/PrinciplesforPHA-ConductedAreaRentSurveys.pdf.*

3. Areas where valid reevaluation requests are submitted *may* continue to use FY 2023 FMRs, or *may* use the FY 2024 FMRs. Commenters should indicate whether they wish to maintain the FY 2023 or implement the FY 2024 FMR during the revaluation period as part of their reevaluation request. Following the comment period, HUD will post a list, at *https://www.huduser.gov/portal/datasets/fmr.html,* of the areas requesting reevaluations where FY 2023 FMRs remain in effect.

4. PHAs or other parties must supply data for reevaluations to HUD no later than Friday January 5, 2024. All survey responses of rental units gathered as part of the survey efforts should be delivered to HUD. In addition to the survey data, HUD requires a current utility schedule to evaluate the survey responses. Finally, HUD encourages PHAs to evaluate their survey data to ensure the survey supports their request. Should PHAs or their contractors undertake this evaluation, HUD requests that this analysis also be submitted.

HUD will use the data delivered by January 5, 2024 to reevaluate the FMRs and following the reevaluation, will post revised FMRs in April of 2024 with an accompanying **Federal Register** notice stating the revised FMRs are available, which will include HUD's responses to comments filed during the comment period for this notice. By January 12, 2024, HUD will post at *https://www.huduser.gov/portal/datasets/fmr.html* a listing of the areas that requested FMR reevaluations and continued effect of the FY2023 FMRs but did not deliver data, making the FY 2024 FMRs effective in these areas. HUD will incorporate any data supporting a change in FMRs supplied after January 5, 2024 into FY 2025 FMRs. Questions on how to conduct FMR surveys may be addressed to the Program Parameters and Research Division at *pprd@hud.gov.*

[13] Although there are no longer 50th percentile FMRs, HUD must calculate 50th percentile rents for the Success Rate Payment Standard under 24 CFR 982.503(e).

For small metropolitan areas without one-year ACS data and non-metropolitan counties, HUD has developed a method using mail surveys that is discussed on the FMR web page: *https://www.huduser.gov/portal/datasets/fmr.html#survey_info.* This method allows for the collection of as few as 100 one-bedroom, two-bedroom, and three-bedroom units.

Other survey methods are acceptable in providing data to support reevaluation requests if the survey method can provide statistically reliable, unbiased estimates of gross rents paid of the entire FMR area. In general, recommendations for FMR changes and supporting data must reflect the rent levels that exist within the entire FMR area and should be statistically reliable.

PHAs in non-metropolitan areas are required to get 100 eligible survey responses, which means they should have at least 5,000 rental units. PHAs may conduct surveys of groups of non-metropolitan counties to increase the number of rental units that are surveyed, but HUD must approve all county-grouped surveys in advance. HUD cautions that the resulting FMRs may not be identical for the counties surveyed; each individual FMR area will have a separate FMR based on the relationship of rents in that area to the combined rents in the cluster of FMR areas. In addition, HUD advises that in counties where FMRs are based on the combined rents in the cluster of FMR areas, HUD will not revise their FMRs unless the grouped survey results show a revised FMR statistically different from the combined rent level.

Survey samples should preferably be randomly drawn from a complete list of rental units for the FMR area. If this is not feasible, the selected sample must be drawn to be statistically representative of the entire rental housing stock of the FMR area. Surveys must include units at all rent levels and be representative by structure type (including single-family, duplex, and other small rental properties), age of housing unit, and geographic location. The current 5-year ACS data should be used as a means of verifying if a sample is representative of the FMR area's rental housing stock. Staff from HUD's Program Parameters and Research Division will work with PHAs in areas requesting re-evaluations to provide the minimum number of survey cases required to ensure that data submitted for re-evaluation represent a statistically valid sample.

A PHA or contractor that cannot obtain the recommended number of sample responses after reasonable efforts should consult with HUD before abandoning its survey; in such situations, HUD may find it appropriate to relax normal sample size requirements, but in no case will fewer than 100 eligible cases be considered.

Calculating Small Area FMRs Using Rent Distributions

Since FY 2016, HUD has provided guidance and data on how to provide data-supported comments on Small Area FMRs using HUD's special tabulations of the distribution of gross rents by unit bedroom count for ZIP Code Tabulation Areas. HUD has not received any such requests since 2017 and is therefore discontinuing the publication of these data.

VII. Environmental Impact

This notice involves the establishment of FMR schedules, which do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Accordingly, the Fair Market Rent Schedules, which will not be codified in 24 CFR part 888, are available at *https://www.huduser.gov/portal/datasets/fmr.html.*

Solomon Greene,

Principal Deputy Assistant Secretary for Policy Development and Research.

Fair Market Rents for the Housing Choice Voucher Program

Schedule B—General Explanatory Notes

Arrangement of FMR Areas and Identification of Constituent Parts

a. The Metropolitan and Non-Metropolitan FMR Area Schedule lists FMRs alphabetically by state, by metropolitan area and by non-metropolitan county within each state and are available at *https://www.huduser.gov/portal/datasets/fmr.html.*

b. The schedule lists the constituent counties (and New England towns and cities) included in each metropolitan FMR area immediately following the listings of the FMR dollar amounts. All constituent parts of a metropolitan FMR area that are in more than one state can be identified by consulting the listings for each applicable state.

c. The schedule lists two non-metropolitan counties alphabetically on each line of the non-metropolitan county listings.

d. Similarly, the schedule lists the New England towns and cities included in a non-metropolitan county immediately following the county name.

[FR Doc. 2023–18402 Filed 8–30–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_MT_FRN_MO# 4500172578]

Public Meeting for the Missouri Basin Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Missouri Basin Resource Advisory Council (RAC) will meet as follows.

DATES: The Missouri Basin RAC will meet on September 18, 2023, from 10 a.m. to 4 p.m. Mountain Time (MT) and on September 19, 2023, from 8 a.m. to 1 p.m. MT.

ADDRESSES: The meetings will take place at the BLM Miles City Field Office, 111 Garryowen Road, Miles City, MT 59301. To accommodate broader participation, the meetings will provide both in-person and virtual attendance options. Individuals that prefer to participate virtually must contact the RAC coordinator by September 14 to request a link.

FOR FURTHER INFORMATION CONTACT: Mark Jacobsen, Missouri Basin RAC Coordinator, BLM Eastern Montana/Dakotas District Office, 111 Garryowen Road, Miles City, MT 59301; telephone: (406) 233–2831; email: *mjacobse@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. 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: The 15-member council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in central and eastern Montana, and North and South Dakota. At this meeting, agenda topics will

include North-Central and Eastern Montana/Dakotas District Office reports, Field Office manager reports, the North Dakota Resource Management Plan, and other topics and items of interest the RAC may wish to cover. The final agenda will be posted on the RAC's web page 1 week in advance of the meeting at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/montana-dakotas/missouri-basin-rac.* All meetings are open to the public, and the public may address or present written comments to the RAC on both meeting dates. The RAC meeting will have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Written comments to the RAC can be emailed in advance to the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least 7 business days prior to the meeting to give the BLM sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Before including your address, phone number, email address, or other personal identifying information in your comments, please 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.

Authority: 43 CFR 1784.4–2.

Kirsten Kaiser,

North Central Montana District Manager.

[FR Doc. 2023–18780 Filed 8–30–23; 8:45 am]

BILLING CODE 4331–20–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–36484; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before August 19, 2023, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by September 15, 2023.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION:

The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before August 19, 2023. Pursuant to section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

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.

Nominations submitted by State or Tribal Historic Preservation Officers.

Key: State, County, Property Name, Multiple Name (if applicable), Address/Boundary, City, Vicinity, Reference Number.

ARKANSAS

Ashley County

Ashley County Courthouse, 205 East Jefferson St., Hamburg, SG100009391

CALIFORNIA

Sacramento County

Montgomery Way Gateway Historic District, 2640–2770 Montgomery Way and 3065, 3071 East Curtis Dr., Sacramento, SG100009396

San Diego County

La Jolla Park Coastal Historic District, From intersection of Coast Walk with Torrey Pines Rd. and following Coast Walk, then Coast Blvd. southwest to its southernmost intersection with South Coast Blvd., La Jolla, SG100009395

Santa Barbara County

Mission La Purísima at 'Amuwu District, (Native Americans and the California Mission System, 1769–1848 MPS), 2295 Purisima Rd., Lompoc, MP100009394

LOUISIANA

Orleans Parish

Hollygrove Historic District, Roughly bounded by Airline Hwy., South Claiborne, South Carrollton, and Monticello Aves., New Orleans, SG100009397

MISSOURI

Greene County

Fallin Garage, (Springfield, Missouri MPS AD), 423 West Olive St., Springfield, MP100009384

SOUTH CAROLINA

Clarendon County

Pleasant Grove School, 1012 Joe and Marie Rd., Alcolu, SG100009383

Greenville County

Greenville Pepsi-Cola Bottling Plant, 705 Poinsett Hwy., Greenville vicinity, SG100009398

Union County

Sims High School, 200 Sims Dr., Union, SG100009382

TEXAS

Travis County

Austin Central Library, 800 Guadalupe St., Austin, SG100009378

St. Martin's Evangelical Lutheran Church, 606 West 15th St., Austin, SG100009392

An owner objection was received for the following resource:

CALIFORNIA

Santa Clara County

Alpha Omega Chapter of Sigma Chi Fraternity House, 550 Lasuen Mall, Stanford, SG100009388

Additional documentation has been received for the following resource:

WYOMING

Sweetwater County

Downtown Rock Springs Historic District, Roughly bounded by K, 4th, C, 2nd, A and 5th Sts., Rock Springs, AD93001492

Authority: Section 60.13 of 36 CFR part 60.

Dated: August 24, 2023.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2023–18878 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036501; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: St. Joseph Museums, Inc., St. Joseph, MO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the St. Joseph Museums, Inc., intends to repatriate a certain cultural item that meets the definition of an unassociated funerary object and certain cultural items that meet the definition objects of cultural patrimony, and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from Lincoln, NE, and from somewhere near St. Louis, MO.

DATES: Repatriation of the cultural items in this notice may occur on or after October 2, 2023.

ADDRESSES: Tori Zieger; St. Joseph Museums, Inc., P.O. Box 8096, St. Joseph, MO 64508, telephone (816) 752–2778, email *tori@stjosephmuseum.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the St. Joseph Museums, Inc. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the St. Joseph Museums, Inc.

Description

Two objects of cultural patrimony were removed from Lincoln, Nebraska. The two objects of cultural patrimony are an Osage ''war'' bundle and a Song List for a Counting Stick. They were purchased by Harry L. George on two separate occasions in 1915. The Harry L. George Collection of approximately 4,000 American Indian items became the cornerstone of the St. Joseph Museum in the 1940s.

One unassociated funerary object was removed from somewhere near St. Louis, Missouri. The unassociated funerary object is a ''wampum''/shell bead necklace with a projectile point. It was collected from a grave in 1889.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archeological, historical, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the St. Joseph Museums, Inc. has determined that:

- One cultural item described above is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Two cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and The Osage Nation.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, the St. Joseph Museums, Inc. must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The St. Joseph Museums, Inc. is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18826 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036490; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Field Museum, Chicago, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Field Museum has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at an unknown location or locations.

DATES: Repatriation of the human remains in this notice may occur on or after October 2, 2023.

ADDRESSES: Helen Robbins, Repatriation Director, Field Museum, 1400 S Lake Shore Drive, Chicago, IL 60605, telephone (312) 665–7317, email *hrobbins@fieldmuseum.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Field Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Field Museum.

Description

Human remains representing, at minimum, four individuals were collected at an unknown location or locations. The human remains are hair clippings belonging to four individuals identified by the tribal designation ''Stockbridge'' (Field Museum catalog numbers 193213.8, 193213.10, 193215.1, and 193216.6). Field Museum staff believe they were collected under

the direction of Franz Boas and Frederick Ward Putnam for the 1893 World's Columbian Exposition in Chicago. The hair clippings were accessioned into the Field Museum's collection in 1939. No information regarding any individual's name, sex, age, or geographic origin has been found. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: historical.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Field Museum has determined that:

- The human remains described in this notice represent the physical remains of four individuals of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Stockbridge Munsee Community, Wisconsin.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, the Field Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The Field Museum is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18819 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036488; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Autry Museum of the American West, Los Angeles, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Autry Museum of the American West has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from San Luis Obispo County, CA.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after October 2, 2023.

ADDRESSES: Karimah Richardson, M.Phil., RPA, Associate Curator of Anthropology and Repatriation Supervisor, Autry Museum of the American West, 4700 Western Heritage Way, Los Angeles, CA 90027, telephone (323) 495–4203, email *krichardson@theautry.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Autry Museum of the American West. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Autry Museum of the American West.

Description

At an unknown date, human remains representing, at minimum, one individual were removed by Mrs. Gladys Knight Harris, a cultural anthropologist from Santa Barbara County, CA, from an unknown site on Morro Bay in San Luis Obispo County, CA. In 1983, Mrs. Knight Harris donated these human remains, together with associated funerary objects, to the Southwest Museum. The human remains, which consist of a mandible, belong to an adult of undetermined sex. The 26 associated funerary objects are 10 shell fragments, six faunal bone fragments, one lot consisting of ochre fragments, and nine shell beads.

Sometime around 1967, human remains representing, at minimum, one individual were removed by Mr. Robert Henze from an unknown site at Ragged Point, located 15 miles north of San Simeon, in San Luis Obispo County, CA. Mr. Henze had found these human remains eroding from Ragged Point, and in 1972, he donated them to the Southwest Museum. The human remains, which consist of a cranium and a mandible, belong to an adult (probably female) between 35 and 50 years old. The one associated funerary object is a lot consisting of soil.

Based on the associated funerary objects, the Autry Museum has determined that these human remains belong to a Native American burial. Moreover, the presence of red ochre, which is a hallmark of Chumash and nearby southern California tribal funerary practice, supports an identification of this burial as Northern Chumash or Salinan.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archeological, geographical, historical, and oral traditional.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Autry Museum of the American Indian has determined that:

- The human remains described in this notice represent the physical

remains of two individuals of Native American ancestry.

• The 27 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

• There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, the Autry Museum of the American West must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Autry Museum of the American West is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18817 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036491; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Field Museum, Chicago, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Field Museum has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at an unknown location or locations.

DATES: Repatriation of the human remains in this notice may occur on or after October 2, 2023.

ADDRESSES: Helen Robbins, Repatriation Director, Field Museum, 1400 S. Lake Shore Drive, Chicago, IL 60605, telephone (312) 665–7317, email *hrobbins@fieldmuseum.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Field Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Field Museum.

Description

Human remains representing, at minimum, four individuals were collected at an unknown location or locations. The human remains are hair clippings belonging to four individuals identified by the tribal designation ''Winnebago'' (Field Museum catalog numbers 193210.9, 193212.7, 193212.8, and 193214.4). Field Museum staff believe they were collected under the direction of Franz Boas and Frederick Ward Putnam for the 1893 World's Columbian Exposition in Chicago. The hair clippings were accessioned into the Field Museum's collection in 1939. No information regarding any individual's name, sex, age, or geographic origin has been found. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: historical.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Field Museum has determined that:

• The human remains described in this notice represent the physical remains of four individuals of Native American ancestry.

• There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Ho-Chunk Nation of Wisconsin and the Winnebago Tribe of Nebraska.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, the Field Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The Field Museum is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18820 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036494; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: HISTORY Fort Lauderdale, Fort Lauderdale, FL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), HISTORY Fort Lauderdale intends to repatriate a certain cultural item that meets the definition of an object of cultural patrimony and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural item was removed from the Great Lakes Region.

DATES: Repatriation of the cultural item in this notice may occur on or after October 2, 2023.

ADDRESSES: Tara Chadwick, HISTORY Fort Lauderdale, 219 SW 2nd Avenue, Fort Lauderdale, FL 33301, email *tchadwick@flhc.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of HISTORY Fort Lauderdale. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by HISTORY Fort Lauderdale.

Description

In 1969, a beaded belt with yarn ties was donated to the Fort Lauderdale Historical Society (HISTORY Fort Lauderdale) by Fulton Wells, who stated that the item had been gifted by ''Connecticut Indians'' to his father, Phillip Wells. After consulting with Indian Tribes in Connecticut and subject matter experts, HISTORY Fort Lauderdale has determined that this item (accession X–281) most likely is associated with the Great Lakes area and not Connecticut. Based on information provided by the Ho-Chunk Nation of Wisconsin, HISTORY Fort Lauderdale also has determined that the beaded panel belt meets the definition of an object of cultural patrimony.

Cultural Affiliation

The cultural item in this notice is connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical, historical, oral traditional, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, HISTORY Fort Lauderdale has determined that:

- The one cultural item described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural item and the Ho-Chunk Nation of Wisconsin.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural item in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, HISTORY Fort Lauderdale must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item is considered a single request and not competing requests. HISTORY Fort Lauderdale is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18822 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036489; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Autry Museum of the American West, Los Angeles, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Autry Museum of the American West intends to repatriate certain cultural items that meet the definition of unassociated funerary objects and a certain cultural item that meets the definition of a sacred object, and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from San Luis Obispo County, CA.

DATES: Repatriation of the cultural items in this notice may occur on or after October 2, 2023.

ADDRESSES: Karimah Richardson, M.Phil., RPA, Associate Curator of Anthropology and Repatriation Supervisor, Autry Museum of the American West, 4700 Western Heritage Way, Los Angeles, CA 90027, telephone (323) 495–4203, email *krichardson@theautry.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Autry Museum of the American West. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Autry Museum of the American West.

Description

In 1896, the Southwest Museum of the American Indian (now part of the Autry Museum of the American West) purchased a collection from the museum's first curator, Dr. Frank M. Palmer. Sometime between 1877 and 1896, Palmer collected cultural items from burials at multiple, unknown sites along the coast of San Luis Obispo County, CA. The coast of San Luis Obispo County is within the aboriginal territory of the Chumash and Salinan people. The Autry Museum does not have possession or control of any

human remains associated with these items. Based on museum records, the Autry Museum has control of 1,510 unassociated funerary objects that Palmer removed from burials. Of this number, 1,476 have been located and 34 currently are missing. The 1,476 unassociated funerary objects are one basket water bottle lined with asphaltum, 10 bird bone beads, one bone tube with traces of asphaltum, one vegetal carved bowl (made from either wood, seed, or gourd), 58 brass and bronze buttons, one brass bell, one brass button, one brass hilt, two charms made from spiral fossils, one charm made from a concretion, one steatite gorget, one historic glass bottle, two chert knives, one neck of basket water bottle asphaltum lined, two cakes of red ochre, one wooden paint cup, one fish vertebral bone paint pot, two pestles, four shell beads made from scallops, one oyster shell spoon, one soap root brush, one steatite bowl, one pestle with ochre staining, one lot consisting of approximately 227 barrel-shaped Olivella and clamshell beads (some of them burned), and 1,379 glass beads. The 34 currently missing unassociated funerary objects are one arrow polisher, one basket bottom, one breast ornament, one burial mat, one carved wood, one charm, six cooking pots, one cooking stone, one disc, one doll body, one fishing line, one head dress, one historic bottle, one knife, one medicine stone, three mortars, two necklaces, one onyx pendant, one pendant, two pestles, two shell spoons, one spear head, one whistle, and one lot consisting of basketry fragments, beads, and bone beads.

In 1935, the Southwest Museum of the American Indian (now the Autry Museum of the American West) was gifted a cultural item by Mr. Clifford Park Baldwin, who worked for the Southwest Museum from 1933 to 1937, in various capacities. Sometime between 1911 and 1935, Mr. Baldwin collected the item from Morro Bay in San Luis Obispo County, CA. Morro Bay is within the aboriginal territory of the Chumash people and Salinan people. During consultation with tribal representatives from the Santa Ynez Band of Chumash Mission Indians of the Sant Ynez Reservation, California, the item was identified as an unassociated funerary object. The one unassociated funerary is a faunal bone hairpin.

In 1939, the Southwest Museum of the American Indian (now the Autry Museum of the American West) was gifted a cultural item by Mr. Willy Stahl, who worked for the Southwest Museum from 1937 to 1948. Mr. Stahl collected the item from Sandspit Beach, near Santa Maria in Santa Maria Valley, CA. Since 1965, the beach has been part of Montana de Oro State Park. Santa Maria Valley is within the aboriginal territory of the Chumash and Salinan people. During consultation with tribal representatives from the Santa Ynez Band of Chumash Mission Indians of the Sant Ynez Reservation, California, the item was identified as an unassociated funerary object. The one unassociated funerary is a faunal bone hairpin fragment.

In 1944, the Southwest Museum of the American Indian (now the Autry Museum of the American West) was gifted a cultural item by Mr. Franklin R. Johnston, an archeologist. Sometime between 1930 and 1944 (inclusive), Johnston collected the item, a small pestle, at his campsite on Pismo Beach, in San Luis Obispo County, CA. Pismo Beach is within the aboriginal territory of the Chumash and Salinan people. During consultation with tribal representatives from the Santa Ynez Band of Chumash Mission Indians of the Sant Ynez Reservation, California, the pestle was identified as a ceremonial object. The Chumash, as well as other southern Californian Indians within the area view small pestles like this one as sacred objects. The one sacred object is a pestle.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archeological, geographical, oral traditional, and historical.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Autry Museum of the American West has determined that:

- The 1,512 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- The one cultural item described above is a specific ceremonial object needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the Santa Ynez Band of Chumash Mission Indians of the Sant Ynez Reservation, California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, the Autry Museum of the American West must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Autry Museum of the American West is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18818 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036500; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: San Francisco State University NAGPRA Program, San Francisco, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the San Francisco State University NAGPRA Program intends to repatriate certain

cultural items that meet the definition of objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from Placer County, CA.

DATES: Repatriation of the cultural items in this notice may occur on or after October 2, 2023.

ADDRESSES: Zay D. Latt, San Francisco State NAGPRA Program, 1600 Holloway Avenue, San Francisco, CA 94132, telephone (415) 405–3545, email *zlatt@sfsu.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the San Francisco State NAGPRA Program. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the San Francisco State NAGPRA Program.

Description

In 1964, cultural items were excavated and removed from sites PLA–1, PLA–14, PLA–25, PLA–H–7, PLA–H–11, PLA–H–12, PLA–19, and PLA–UNK in Placer County, CA. Upon the closure of the Tregenza Anthropology Museum in 2012, the cultural items were transferred to the San Francisco State University NAGPRA program. The objects of cultural patrimony are 15 lots consisting of modified stone, modified metal, and other objects.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: oral traditional, anthropological, archeological, geographical, historical, linguistic, other relevant information, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the San Francisco State NAGPRA Program has determined that:

- The 15 cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the United Auburn Indian Community of the Auburn Rancheria of California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, the San Francisco State NAGPRA Program must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of cultural items are considered a single request and not competing requests. The San Francisco State NAGPRA Program is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18825 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036497; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, Bureau of Land Management, Anchorage, AK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of the Interior, Bureau of Land Management (BLM Alaska) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were removed from a site in the Yukon Willow Creek area about 25 miles south of Nulato, AK, in the Yukon-Koyukuk Census Area, AK.

DATES: Repatriation of the human remains in this notice may occur on or after October 2, 2023.

ADDRESSES: Robert E. King, Bureau of Land Management, 222 W. 7th Avenue, #13, Anchorage, AK 99513, telephone (907) 271–5510, email *r2king@blm.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of BLM Alaska. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by BLM Alaska.

Description

In 1935, human remains representing, at minimum, one individual were removed from the Yukon Willow Creek site in the middle Yukon Valley, about 25 miles south of Nulato, AK. The human remains, which are estimated to be over 200 years old, were removed by Frederica de Laguna, who at that time was associated with the University of Pennsylvania Museum of Archaeology and Anthropology in Philadelphia, PA. The human remains were brought back to the Museum, where they are currently being held in collections [PM# 35–21–149]. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archeological and oral traditional.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate

Indian Tribes and Native Hawaiian organizations, BLM Alaska has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Nulato Village.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, BLM Alaska must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. BLM Alaska is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18824 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036492; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Field Museum, Chicago, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Field Museum intends to repatriate certain cultural items that meet the definition of unassociated funerary objects, sacred objects, and objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from Kings County, CA.

DATES: Repatriation of the cultural items in this notice may occur on or after October 2, 2023.

ADDRESSES: Helen Robbins, Field Museum, 1400 S. Lake Shore Drive, Chicago, IL 60605–2496, telephone (312) 665–7317, email *hrobbins@fieldmuseum.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Field Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Field Museum.

Description

The 25 cultural items listed in this notice were removed from Kings County, CA. In May and June of 1901, Dr. John Hudson collected the cultural items on behalf of the Field Museum during a two-year expedition among the Native populations of California. That same year, the Field Museum accessioned these cultural items. Two of the cultural items are unassociated funerary objects. They are one lot consisting of shells and wampum, and one glass bead necklace. Nine of the cultural items are sacred objects. They are one dance clapper, one headdress, one roll of eagle down, one head net, one skirt, one hand wand, one bunch of eagle down, one lot consisting of white paint, and one roll of jay feathers. Fourteen of the cultural items are objects of cultural patrimony. They are one wooden mortar, two stone mortars, three sifting trays, one cooking basket, one small basket, one digging stick, one bone awl, one set of quiver and arrows, and three drills.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, geographical, historical, oral traditional, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Field Museum has determined that:

- Two of the cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Nine of the cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Fourteen of the cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, the Field Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Field Museum is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25

U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18821 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036496; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: The Children's Museum of Indianapolis, Indianapolis, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), The Children's Museum of Indianapolis intends to repatriate certain cultural items that meet the definition of sacred objects and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from Pine Ridge, South Dakota.

DATES: Repatriation of the cultural items in this notice may occur on or after October 2, 2023.

ADDRESSES: Jennifer Noffze, The Children's Museum of Indianapolis, 3000 N. Meridian Street, Indianapolis, IN 46208, telephone (317) 334–3722, email *jenn@childrensmuseum.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of The Children's Museum of Indianapolis. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by The Children's Museum of Indianapolis.

Description

In 1948, Anna Russell donated one tobacco bag to The Children's Museum of Indianapolis. The bag came from Pine Ridge, South Dakota, and it was made sometime between 1880 and 1910. The main body of the bag has a beaded decoration of a red cross on a white field, and the bottom of the bag is decorated with rawhide strips wrapped with quillwork.

In 1937, Mrs. R.S. Foster donated one tobacco bag to The Children's Museum of Indianapolis. The bag came from Pine Ridge, South Dakota, and it was made sometime between 1880 and 1890. The bag is decorated with 14 rows of beadwork and fringes comprised of quill-wrapped tassels ending in metal cones topped by red horsehair tufts, and the bottom of the bag is decorated with red, green, orange, and violet quills wrapped around 26 rawhide slats.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical, historical, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, The Children's Museum of Indianapolis has determined that:

- The two cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the Oglala Sioux Tribe.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after October 2, 2023. If competing requests for repatriation are received, The Children's Museum of Indianapolis must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Children's Museum of Indianapolis is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: August 23, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18823 Filed 8–30–23; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1185 (Second Review)]

Steel Nails From the United Arab Emirates

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on steel nails from the United Arab Emirates would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on September 1, 2022 (87 FR 53777) and determined on December 5, 2022 that it would conduct a full review (87 FR 79907, December 28, 2022). Notice of the scheduling of the Commission's review and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on February 9, 2023 (88 FR 8457). The Commission conducted its hearing on June 29, 2023. All persons who requested the opportunity were permitted to participate.

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on August 28, 2023. The

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

views of the Commission are contained in USITC Publication 5454 (August 2023), entitled *Steel Nails from the United Arab Emirates: Investigation No. 731–TA–1185 (Second Review).*

By order of the Commission.

Issued: August 28, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–18855 Filed 8–30–23; 8:45 am]

BILLING CODE 7020–02–P

MERIT SYSTEMS PROTECTION BOARD

Privacy Act of 1974; System of Records

AGENCY: Merit Systems Protection Board.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the U.S. Merit Systems Protection Board (MSPB) proposes to establish a new system of records titled ''MSPB–4, Emergency Alert System.'' This system of records includes information that MSPB collects, maintains, and uses for operational response to critical events to ensure the safety and security of MSPB personnel and physical locations, as well as to keep MSPB personnel up to date on emergencies that may impact MSPB personnel and operations, such as active shooter situations, terrorist attacks, or severe weather conditions.

DATES: Please submit comments on or before October 2, 2023. This new system is effective upon publication in today's **Federal Register**, with the exception of the routine uses, which are effective October 2, 2023.

ADDRESSES: You may submit written comments to the Office of the Clerk of the Board by email to *privacy@mspb.gov* or by mail to Clerk of the Board, U.S. Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419. All comments must reference ''MSPB–4, Emergency Alert System SORN.'' Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to MSPB's website (*https://www.mspb.gov*) and will include any personal information you provide, such as your name, address, phone number, email address, or any other personally identifying information in your comment or materials. Therefore, any submissions will be made public and without change.

FOR FURTHER INFORMATION CONTACT: For general questions or privacy issues, please contact: D. Fon Muttamara, Chief Privacy Officer, Office of the Clerk of the Board, 1615 M Street NW, Washington, DC 20419; (202) 653–7200; *privacy@mspb.gov.* Please include ''MSPB–4 Emergency Alert System'' with your question(s).

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the MSPB proposes to establish a new system of records titled ''MSPB–4, Emergency Alert System.'' MSPB's Office of Financial and Administrative Management (FAM) is responsible for, among other things, the security of personnel and physical locations. This system of records includes information that MSPB collects, maintains, and uses for operational response to critical events to ensure the safety and security of MSPB personnel and physical locations, as well as to keep MSPB personnel up to date on emergencies that may impact MSPB personnel and operations, such as active shooter situations, terrorist attacks, or severe weather conditions.

The Privacy Act embodies fair information practice principles in a statutory framework governing how Federal agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to records about individuals that are maintained in a ''system of records.'' A system of records is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act defines an individual as a United States citizen or lawful permanent resident. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of MSPB by complying with MSPB Privacy Act regulations at 5 CFR part 1205, and following the procedures outlined in the Records Access, Contesting Record, and Notification Procedures sections of this notice. The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the existence and character of each system of records that the agency maintains and the routine uses of each system. The new ''Emergency Alert System'' System of Records Notice is published in its entirety below. In accordance with the Privacy Act, 5 U.S.C. 552a(r), and OMB Circular A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act'' (Dec. 2016), MSPB has submitted a report of a new system of records to the Office of Management and Budget and Congress.

Jennifer Everling,

Acting Clerk of the Board, U.S. Merit Systems Protection Board.

SYSTEM NAME AND NUMBER:

MSPB–4, Emergency Alert System.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained by the Office of Financial and Administrative Management, U.S. Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419. Records may be located in locked cabinets and offices, on MSPB's local area network, or in designated U.S. data centers for cloud service providers certified by the Federal Risk and Authorization Management Program or FedRAMP.

SYSTEM MANAGER(S):

Kevin Nash, Director of the Office of Financial and Administrative Management, U.S. Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419, *kevin.nash@mspb.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 1204; Federal Continuity Directive (FCD) 1, Federal Executive Branch National Continuity Program and Requirements, January 17, 2017; FCD 2, Federal Executive Branch Mission Essential Functions and Candidate Primary Mission Essential Functions Identification and Submission Process, June 13, 2017; Directive on National Continuity Policy (National Security Presidential Directive 51/Homeland Security Presidential Directive 20), May 4, 2007.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system of records is to allow MSPB to collect and maintain records of employees who receive emergency alerts.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former employees of MSPB.

CATEGORIES OF RECORDS IN THE SYSTEM:

1. MSPB employee name;
2. MSPB email addresses;
3. MSPB-assigned office phone numbers;
4. MSPB-issued mobile device numbers;
5. Personal email addresses (if provided);
6. Personal home phone numbers (if provided); and

7. Personal mobile device numbers (if provided).

RECORD SOURCE CATEGORIES:

Information contained in this system is obtained from MSPB's Office of Information Resources Management (IRM). IRM will provide a .csv file to FAM, the .csv file will contain MSPB employee email addresses and MSPB-assigned office phone numbers (and extensions if applicable) from MSPB's Microsoft Active Directory, as well as MSPB-issued mobile device numbers. FAM will then provide the file to Everbridge (the emergency alert system vendor) through MSPB's secure file sharing system, *Box.com.* As new hires onboard at MSPB, FAM will manually enter the required PII into the Everbridge system. Additionally, FAM will manually delete the PII of departing employees 30 days from departure. Employees may voluntarily provide personal contact information, which FAM will add to the information maintained in Everbridge for those employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside MSPB as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys; or another Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body; another party or potential party or the party's or potential party's authorized representative in litigation before a court, adjudicative, or administrative body; or to a court, adjudicative, or administrative body. Such disclosure is permitted only when it is relevant or necessary to the litigation or proceeding, and one of the following is a party to the litigation or has an interest in such litigation:

(1) MSPB, or any component thereof;

(2) Any employee or former employee of MSPB in his or her official capacity;

(3) Any employee or former employee of MSPB in his or her individual capacity where DOJ or MSPB has agreed to represent the employee;

(4) The United States or a Federal agency in litigation before a court, adjudicative, or administrative body;

(5) A party, other than the United States or a Federal agency, in litigation before a court, adjudicative, or administrative body, upon the MSPB General Counsel's approval, pursuant to 5 CFR part 1216 or otherwise.

b. To the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates or is relevant to a violation or potential violation of civil or criminal law or regulation.

c. To a member of Congress or the White House from the record of an individual in response to an inquiry made at the request of the individual to whom the record pertains.

d. To the National Archives and Records Administration (NARA) in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

e. To appropriate agencies, entities, and persons when (1) MSPB suspects or has confirmed that there has been a breach of the system of records; (2) MSPB has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, MSPB (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with MSPB's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

f. To another Federal agency or Federal entity, when MSPB determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

g. To contractors, grantees, experts, consultants, or volunteers performing or working on a contract, service, grant, cooperative agreement, or other assignment for MSPB when MSPB determines that it is necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to MSPB employees.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The records in this system of records are stored electronically on an MSPB vendor's system(s) to facilitate the administration of the alerts. Access is limited to a small number of authorized personnel at MSPB and at MSPB's vendor.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name or other unique personal identifier.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The records maintained in this system of records are subject to NARA General Records Schedule 5.4. Records of departing employees will be removed from the system by FAM 30 days after departure from MSPB. The information will be removed from the Everbridge servers after 30 days once the contract is completed.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in the system are protected from unauthorized access and misuse through various administrative and technical security measures, such as role-based access controls, mandatory security and privacy training, encryption, and multi-factor authentication.

RECORD ACCESS PROCEDURES:

Individuals seeking notification of and access to their records in this system of records may submit a request in writing to the Office of the Clerk of the Board, Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419. Individuals requesting access must comply with MSPB's Privacy Act regulations regarding verification of identity and access to records (5 CFR part 1205).

CONTESTING RECORD PROCEDURES:

Individuals may request that records about them be amended by writing to the Office of the Clerk of the Board, Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419. Individuals requesting amendment must follow MSPB's Privacy Act regulations regarding verification of identity and amendment to records (5 CFR part 1205).

NOTIFICATION PROCEDURES:

See Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2023–18848 Filed 8–30–23; 8:45 am]

BILLING CODE 7401–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[NOTICE: 23–091]

Conflict of Interest Policy for Recipients of NASA Financial Assistance Awards

AGENCY: National Aeronautics and Space Administration

ACTION: Final notice of a new NASA policy and term and condition regarding conflict of interest disclosures for grant and cooperative agreement recipients.

SUMMARY: The National Aeronautics and Space Administration (NASA) is publishing, in final form, a new policy and term and condition regarding conflict of interest disclosures. The final policy can be found in Grant Information Circular (GIC) 23–07. NASA's intention to develop and implement this new policy and term and condition was specified in the **Federal Register** of January 30, 2023.

FOR FURTHER INFORMATION CONTACT: For any questions, comments, or concerns regarding this policy, please contact Christopher Murguia at *christopher.e.murguia@nasa.gov* or 202–909–5918.

SUPPLEMENTARY INFORMATION:

Background

In December 2020, the U.S. Government Accountability Office (GAO) published report GAO–21–130, *Federal Research: Agencies Need to Enhance Policies to Address Foreign Influence.* This report included two recommendations for NASA that pertained to (1) updating NASA's conflict of interest policy to include a definition of non-financial conflicts, such as conflicts of commitment, and (2) documenting procedures, roles, and responsibilities for addressing and enforcing failures to disclose required information. In response to GAO–21–130, NASA published a proposed conflict of interest and conflict of commitment policy in the **Federal Register** in January 2023 (88 FR 5930, pages 5930–5932, January 30, 2023). After reviewing public comments and feedback, NASA has revised the proposed policy to only address financial conflicts of interest. All references to conflicts of commitment in the January 2023 draft policy have been removed.

The revised policy is designed to standardize NASA's conflict to interest disclosure requirements with those of other Federal research funding agencies. In summary, the policy requires NASA grant and cooperative agreement recipients to maintain and enforce a conflict of interest policy that requires the disclosure of significant financial interests to an authorized official prior to application submission. Prior to the expenditure of grant or cooperative agreement funds, the institution shall review disclosed significant financial interests, determine if a conflict of interest exits, and determine what conditions or restrictions, if any, should be imposed to manage, reduce, or eliminate such conflict of interest. Institutions shall notify NASA of any conflict of interest that cannot be managed, reduced, or eliminated in accordance with the institution's policy.

Public Comments Discussion

In response to NASA's request for public comment, the Agency received seven letters containing multiple comments from colleges and universities, for-profit entities, and other non-profit organizations. All comments were carefully reviewed and considered prior to finalizing the policy.

NASA received several comments pertaining to the lack of consistency between the Agency's proposed conflict of interest and conflict of commitment policy and other agencies' conflict of interest policies. Commenters stated that this lack of consistency could result in award recipients having to adopt unique processes, tools, and training to address unique requirements in NASA's proposed policy. *Response:* NASA recognizes the inconsistencies between the proposed policy and that of other Federal research agencies and the confusion that those inconsistencies may cause. As such, NASA has aligned its conflict of interest policy with those of other Federal research agencies to the greatest extent practicable.

Several comments pertained to the conflation of conflicts of interest and conflicts of commitment in NASA's proposed policy. Conflicts of interest and commitment affect research in different ways and, therefore, actions taken to address conflicts of interest are different than those taken to address conflicts of commitment. As such, commenters recommended that NASA address conflicts of interest via a standalone policy similar to other agencies' financial conflicts of interest policies and address conflicts of commitment via biographical sketch and current and pending support disclosures. *Response:* NASA recognizes that conflicts of interest and commitment affect research and are addressed in different ways. Therefore, NASA has removed all references to conflicts of commitment in its policy so as not to conflate the two concepts.

Some comments pertained to the definitions of ''conflict of interest'', ''conflict of commitment'', and ''covered individual'' in the proposed policy. Comments stated that the definitions were vague and inconsistent with terminology and definitions used by other Federal research agencies. Moreover, commenters requested that a definition of ''significant financial interest'' be added to the policy and that that definition include dollar thresholds for what should and should not be considered a significant financial interest. *Response:* NASA has updated the definition of ''conflict of interest'' to align to that used by other Federal research agencies, removed all references to conflicts of commitment, and added a definition for ''significant financial interest'' that includes dollar thresholds.

A few comments requested that NASA revise the time at which conflict of interest information had to be reviewed and managed. Per the comments, other Federal agencies require that significant financial interest disclosures be reviewed and managed, as necessary, prior to the expenditure of award funds. NASA's proposed policy, on the other hand, required conflict of interest information to be reviewed and managed prior to application submission. *Response:* NASA recognizes that its proposed policy included requirements for the review and management of conflict of interest information that is burdensome and inconsistent with other Federal research agencies. NASA has revised the policy to require that significant financial interest disclosures be reviewed and managed, reduced, or eliminated prior to the expenditure of awards funds.

One comment requested that NASA clarify how its proposed policy would impact subaward recipients. *Response:* NASA has added language to the policy describing pass-through entities' and subaward recipients' responsibilities.

One comment recommended that NASA add language to the proposed policy specifically allowing the use of independent third party or contracted services for the provision of technical assistance to meet the due diligence and review requirements described in the policy.

Response: NASA has declined to add this recommended language to the policy. As written, the policy permits discretion when grant and cooperative

agreement recipients are determining which individual(s) is responsible for soliciting and reviewing significant financial interest disclosures.

One comment recommended that the proposed policy be updated to include language allowing security review requirements to be considered a direct cost or, at a minimum, considered a reasonable and allocable cost under title 2 of the Code of Federal Regulations part 200, sections 404 and 405.

Response: NASA assumes that this comment was made in response to language in the proposed policy's definition of conflicts of commitment that pertained to conflicting obligations that threaten research security. Given that all references to conflicts of commitment have been removed, NASA has declined to add this recommended language.

The full text of the policy and term and condition is provided below:

GCAM section 3.3, Conflicts of Interest Policy, is revised as follows:

1. For the purposes of section 3.3, the following definitions apply:

a. The term ''conflict of interest,'' or ''COI,'' means a situation in which an investigator, or the investigator's spouse or dependent children, has a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NASA-funded research.

b. The term ''significant financial interest'' means anything of monetary value, including, but not limited to, salary and any payment for services not otherwise identified as salary (*e.g.,* consulting fees or honoraria), equity interest (*e.g.,* stock, stock options, private equity, or other ownership interests), venture or other capital financing, and intellectual property rights (*e.g.,* patents, copyrights, and royalties from such rights). The term does not include the following:

i. Salaries, royalties, or other remuneration paid by the proposing institution to the investigator if the investigator is currently employed or otherwise appointed by the institution;

ii. Any ownership interests in the proposing institution if the institution is a commercial or for-profit organization;

iii. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;

iv. Income from seminars, lectures, or teaching engagements sponsored by a public or nonprofit entity;

v. Income from service on advisory committees or review panels for a public or nonprofit entity;

vi. An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: (1) does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value and (2) does not represent more than a 5 percent ownership interest in any single entity; or

vii. Salaries, royalties, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed $10,000 during the prior twelve-month period.

c. The term ''institution'' means any domestic or foreign, public or private, entity or organization that is applying for, or that receives, a NASA research grant or cooperative agreement.

d. The term ''investigator'' means the principal investigator, project director, and any other person, regardless of title or position, identified on the proposed project who is responsible for the design, conduct, or reporting of research funded or proposed for funding by NASA.

2. All recipients of NASA research grants and cooperative agreements (hereinafter ''award'') shall maintain a written and enforced policy addressing COI. Pass-through entities shall be responsible for ensuring that (1) subaward recipients have their own policies in place that meet the requirements of NASA's COI policy or (2) investigators working for subaward recipients follow the COI policies of the pass-through entity.

3. Institutions' COI policies shall:

a. Designate an official(s) to solicit disclosures of significant financial interests (including those of the investigator's spouse and dependent children) of investigators that would reasonably appear to be affected by research funded or proposed to be funded by NASA or in entities whose financial interests would reasonably appear to be affected by such activities.

b. Ensure that investigators who are planning to participate in NASA-funded research disclose to the institution's designated official(s) the investigator's significant financial interests no later than the time of application for NASA-funded research. Institutions must also require that disclosures are updated during the award's period of performance, either on an annual basis, or as new reportable significant financial interests are obtained.

c. Prior to an institution's expenditure of any funds under a NASA-funded research award, institutions shall require the designated official(s) to review investigators' disclosures of significant financial interests, determine whether a COI exists, and, if so, determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such COI. Examples of conditions or restrictions that an institution or subrecipient might impose to manage, reduce, or eliminate a conflict include, but are not limited to:

i. Public disclosure of the COI (*e.g.,* when presenting or publishing the research),

ii. Monitoring of research by independent reviewers,

iii. Modification of the research plan,

iv. Change of personnel or personnel responsibilities,

v. Disqualification of personnel from participation in all or a portion of the NASA-funded activity,

vi. Divestiture of significant financial interests that create the COI (*e.g.,* sale of an equity interest), or

vii. Severance of relationships that create the COI.

d. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure investigators' compliance as appropriate.

e. Institutions may apply COI disclosure standards that are more stringent than section 3.3 of this Manual (*e.g.,* standards that require more extensive disclosure of financial interests).

4. Institutions shall adhere to the following notification requirements:

a. Prior to the expenditure of any funds under a NASA-funded research award, institutions shall notify the NASA Grant Officer(s) listed on the related award(s) in writing of any COI that cannot be satisfactorily managed, reduced, or eliminated in accordance with the institution's policy. In cases in which an institution identifies a COI and manages, reduces, or eliminates it prior to the expenditure of NASA-awarded funds, the institution shall not submit a COI notification to NASA.

b. After the expenditure of award funds, institutions shall notify NASA within 60 days of any subsequently identified COI that cannot be managed, reduced, or eliminated.

c. Notifications shall include sufficient information to enable NASA to understand the nature and extent of the COI (*e.g.,* award number, name of investigator with the COI, nature of the significant financial interest, etc.).

5. When an institution notifies a NASA Grant Officer(s) of a COI that cannot be eliminated, managed, or reduced, the cognizant Grant Officer or one of their delegates will report the conflict to the Office of the General Counsel (OGC) as follows:

a. Grant Officers will report the conflict to the NASA Shared Services Center's (NSSC) OGC and copy the award's Technical Officer. The NSSC OGC then will inform HQ OGC of the reported conflict. In consultation with OGC and the relevant Technical Officer, the Grant Officer must review the COI and take appropriate action, as necessary.

i. When an institution notifies NASA of a COI that involves any foreign governments, their instrumentalities, or any other entities owned, funded, or otherwise controlled by a foreign government, the cognizant Grant Officer must review the COI and take appropriate action, as necessary, in consultation with the award's Technical Officer, OGC, and the NASA Office of International and Interagency Relations (OIIR).

ii. If fraud, misrepresentation, or related misconduct is suspected in relation to any COI notification submitted to NASA, then the Grant Officer or Technical Officer also will refer the matter to the NASA Office of Inspector General and OGC's Acquisition Integrity Program.

b. If a Grant Officer must take appropriate actions after conducting the reviews described above, then they will do so in accordance with the remedies for noncompliance and termination provisions in 2 CFR 200.339 through § 200.343. Remedies for noncompliance include but are not limited to:

i. Temporarily withholding payment,

ii. Disallowing all or part of the cost of an award activity,

iii. Wholly or partly suspending or terminating the award,

iv. Initiating referrals for consideration of suspension or debarment proceedings, and

v. Withholding further Federal awards for the project or program.

c. A Grant Officer intending to take action per paragraph (b) of this section, with the exception of paragraph (b)(iv), will notify each institution about the specific reason for the action and will adhere to the requirements in GCAM section 7.13, Appealing a Suspended or Terminated Award, as necessary. However, notice of suspension or debarment proceedings will be issued consistent with 2 CFR part 180, as adopted by NASA at 2 CFR part 1880. Additionally, if NASA determines that an investigator will be disqualified from participating on an award due to a COI that cannot be managed, reduced, or eliminated, then NASA will offer the institution an opportunity to address the COI prior to taking action on the award.

Appendix D, Award Terms and Conditions, is revised as follows:

D39. Conflict of Interest Policy Requirements

a. All NASA grant and cooperative agreement recipients shall comply with the conflict of interest policy and notification requirements in section 3.3, Conflicts of Interest Policy, of the NASA *Grant and Cooperative Agreement Manual* (GCAM), as amended by Grant Information Circular 23–07, Conflict of Interest Policy.

End of Policy and Term and Condition

NASA has implemented the new policy and term and condition through GIC 23–07, which modifies sections 3.3, Conflicts of Interest Policy, and Appendix D, Award Terms and Conditions, of the *Grant and Cooperative Agreement Manual.* The policy and term and condition are effective December 1, 2023, and the term and condition will be placed into new and amended awards at that time.

Antanese Crank,

Chief, Grants Policy and Compliance.

[FR Doc. 2023–18802 Filed 8–30–23; 8:45 am]

BILLING CODE 7510–13–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2023–99]

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:* September 1, 2023.

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) 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).:* CP2023–99; *Filing Title:* USPS Notice of Amendment to Priority Mail and Parcel Select Contract 7, Filed Under Seal; *Filing Acceptance Date:* August 24, 2023; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* September 1, 2023.

[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).

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–18779 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2019–211]

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:* September 6, 2023.

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) 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).:* CP2019–211; *Filing Title:* USPS Notice of Amendment to Parcel Select Contract 34, Filed Under Seal; *Filing Acceptance Date:* August 25, 2023; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* September 6, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–18845 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 22, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 6 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–237, CP2023–240.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18790 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 23, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 37 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–245, CP2023–248.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18784 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

[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).

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 23, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 41 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–249, CP2023–252.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18788 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 22, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 35 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–243, CP2023–246.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18782 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 21, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 31 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–236, CP2023–239.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18793 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 23, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 36 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–244, CP2023–247.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18783 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 23, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 39 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–247, CP2023–250.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18786 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 21,

2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Ground Advantage® Contract 2 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–238, CP2023–241.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18791 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 22, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 34 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–242, CP2023–245.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18796 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 23, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 40 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–248, CP2023–251.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18787 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 22, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 32 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–239, CP2023–242.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18794 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 21, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 5 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–235, CP2023–238.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18789 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 22, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 33 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–241, CP2023–244.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18795 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 23, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 38 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–246, CP2023–249.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18785 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 22, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 785 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–240, CP2023–243.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–18792 Filed 8–30–23; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34992]

Deregistration Under Section 8(f) of the Investment Company Act of 1940

August 25, 2023.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice of applications for reregistration under section 8(f) of the Investment Company Act of 1940.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of August 2023. A copy of each application may be obtained via the Commission's website by searching for the applicable file number listed below, 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. An order granting each application will be issued unless the SEC 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 relevant applicant 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 SEC by 5:30 p.m. on September 19, 2023, and should be accompanied by proof of service on 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 writing to the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.*

FOR FURTHER INFORMATION CONTACT: Shawn Davis, Assistant Director, at (202) 551–6413 or Chief Counsel's Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE, Washington, DC 20549–8010.

BlackRock Maryland Municipal Bond Trust [File No. 811–21051]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniYield Quality Fund, Inc., and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $184,515 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock Massachusetts Tax-Exempt Trust [File No. 811–07660]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniYield Quality Fund, Inc., and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $187,103 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock Municipal Bond Trust [File No. 811–21036]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniHoldings Fund, Inc., and on April 1, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $242,014 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock Municipal Income Investment Quality Trust [File No. 811–21180]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has

transferred its assets to BlackRock MuniHoldings Fund, Inc., and on April 1, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $223,586 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock Municipal Income Investment Trust [File No. 811–10333]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock Municipal Income Trust II, and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $216,777 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock MuniEnhanced Fund, Inc. [File No. 811–05739]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniYield Quality Fund, Inc., and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $280,313 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock MuniHoldings Fund II, Inc. [File No. 811–08215]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniHoldings Fund, Inc., and on April 1, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $229,956 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock MuniHoldings Investment Quality Fund [File No. 811–08349]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock Municipal Income Fund, Inc., and on May 2, 2022 made a final distribution to its shareholders based on net asset value. Expenses of $478,610 incurred in connection with the reorganization were paid by the applicant and the applicant's investment adviser.

BlackRock MuniHoldings Quality Fund, Inc. [File No. 811–08707]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniHoldings Fund, Inc., and on April 1, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $227,958 incurred in connection with the reorganization were paid by the applicant and the applicant's investment adviser.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock MuniYield Arizona Fund, Inc. [File No. 811–07083]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniYield Quality Fund, Inc., and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $194,782 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock MuniYield California Fund, Inc. [File No. 811–06499]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniHoldings California Quality Fund, Inc., and on May 2, 2022 made a final distribution to its shareholders based on net asset value. Expenses of $377,809 incurred in connection with the reorganization were paid by the applicant and the applicant's investment adviser.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock MuniYield California Quality Fund, Inc. [File No. 811–06692]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniHoldings California Quality Fund, Inc., and on May 2, 2022 made a final distribution to its shareholders based on net asset value. Expenses of $415,589 incurred in connection with the reorganization were paid by the applicant and the applicant's investment adviser.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock MuniYield Investment Fund [File No. 811–06502]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniYield Quality Fund, Inc., and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $235,725 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock MuniYield Investment Quality Fund [File No. 811–07156]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock Municipal Income Trust II, and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $210,365 incurred in connection with the reorganization were paid by the applicant and the applicant's investment adviser.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock MuniYield New Jersey Fund, Inc. [File No. 811–06570]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock MuniHoldings New Jersey Quality Fund, Inc., and on May 2, 2022 made a final distribution to its shareholders based on net asset value. Expenses of $414,103 incurred in connection with

the reorganization were paid by the applicant and the applicant's investment adviser.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock New York Municipal Income Quality Trust [File No. 811–21179]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock New York Municipal Income Trust, and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $149,154 incurred in connection with the reorganization were paid by the applicant and the applicant's investment adviser.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock New York Municipal Income Trust II [File No. 811–21124]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock New York Municipal Income Trust, and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $134,844 incurred in connection with the reorganization were paid by the applicant and the applicant's investment adviser.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

BlackRock Strategic Municipal Trust [File No. 811–09401]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock Municipal Income Trust II, and on May 3, 2021 made a final distribution to its shareholders based on net asset value. Expenses of $210,319 incurred in connection with the reorganization were paid by the applicant and the applicant's investment adviser.

Filing Date: The application was filed on July 21, 2023.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

Hartford Funds NextShares Trust [File No. 811–23215]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On June 11, 2019, applicant made a liquidating distribution to its shareholders based on net asset value. Expenses of $21,000 incurred in connection with the liquidation were paid by the applicant's investment adviser.

Filing Date: The application was filed on July 6, 2023.

Applicant's Address: 690 Lee Road, Wayne, Pennsylvania 19087.

USCF Mutual Funds Trust [File No. 811–23213]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On March 21, 2019, applicant made a liquidating distribution to its shareholders based on net asset value. Expenses of $10,000 incurred in connection with the liquidation were paid by the applicant's investment adviser.

Filing Date: The application was filed on July 28, 2023.

Applicant's Address: 1850 Mt. Diablo Boulevard, Suite 640, Walnut Creek, California 94596.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–18771 Filed 8–30–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98227; File No. SR–DTC–2023–801]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Advance Notice To Raise Prefunded Liquidity Resources Through the Periodic Issuance and Private Placement of Senior Notes

August 25, 2023.

Pursuant to section 806(e)(1) of title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i) under the Securities Exchange Act of 1934 (''Act''),[2] notice is hereby given that on August 15, 2023, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') the advance notice SR–DTC–2023–801 (''Advance Notice'') as described in Items I, II and III below, which Items have been prepared by the clearing agency. The Commission is publishing this notice to solicit comments on the Advance Notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This advance notice is filed by DTC in connection with a proposal to raise prefunded liquidity resources through the periodic issuance and private placement of senior notes (''Debt Issuance''). The proceeds from the Debt Issuance would supplement DTC's existing default liquidity risk management resources, as described in greater detail below.[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the Advance Notice and discussed any comments it received on the Advance Notice. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A and B below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice Received from Members, Participants, or Others

Written comments on the advance notice have not been solicited or received. DTC will notify the Commission of any written comments received by DTC.

(B) Advance Notice Filed Pursuant to Section 806(e) of the Clearing Supervision Act

Description of Proposed Change

DTC is proposing to raise prefunded liquidity through the periodic issuance and private placement of senior notes to qualified institutional investors in an aggregate amount not to exceed $5 billion, as described in greater detail below. The proceeds of the Debt Issuance would supplement DTC's qualifying liquidity resources, which are described in the Clearing Agency Liquidity Risk Management Framework (''Framework'') [4] and include cash

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] Capitalized terms not defined herein are defined in the Rules, By-Laws and Organization Certificate of DTC (''Rules'') available at *www.dtcc.com/~/media/Files/Downloads/legal/rules/dtc_rules.pdf*.

[4] *See* Securities Exchange Act Release Nos. 82377 (Dec. 21, 2017), 82 FR 61617 (Dec. 28, 2017) (SR–DTC–2017–004; SR–FICC–2017–008; SR–NSCC–2017–005). Following the completion of the initial

Continued

deposits to its Participants Fund and cash that would be obtained by drawing upon DTC's committed 364-day credit facility with a consortium of banks (''Line of Credit'').[5]

More precisely, while the specific terms of any future Debt Issuance would depend on a number of factors, as described in greater detail below, DTC is requesting the authority to use the proceeds of any Debt Issuance as default liquidity.[6]

DTC, along with its affiliates, National Securities Clearing Corporation (''NSCC'') and Fixed Income Clearing Corporation (''FICC,'' and, together with NSCC and DTC, the ''Clearing Agencies''), maintain the Framework which sets forth the manner in which DTC measures, monitors and manages the liquidity risks that arise in or are borne by it.[7] DTC's liquidity risk management strategy and tools are designed to maintain sufficient available liquid resources to complete system-wide settlement on each business day, with a high degree of confidence and notwithstanding the failure to settle of the Participant, or affiliated family of Participants, with the largest settlement obligation.[8]

The proposed Debt Issuance would provide DTC with an additional source of default liquidity, which would allow it to diversify its sources of default liquidity and mitigate risks to DTC that it is unable to secure default liquidity resources in an amount necessary to meet its liquidity needs. DTC utilizes certain rules-based tools, including the Net Debit Cap and the Collateral Monitor, to manage the liquidity risks its Participants' present to it.[9] These two controls work together to protect the DTC settlement system in the event of a Participant default. The Collateral Monitor requires net debit settlement obligations, as they accrue intraday, to be fully collateralized and the Net Debit Cap limits the amount of any Participant's net debit settlement obligation to an amount that can be satisfied with DTC's default liquidity resources. As stated above, DTC currently maintains two key default liquidity resources to draw upon in the event of a Participant default: cash deposits to its Participants Fund and cash that would be obtained by drawing upon the Line of Credit.[10] By allowing DTC to diversify its sources of default liquidity, the proposal would mitigate the risk, for example, that DTC is unable to renew its Line of Credit at the targeted amount by providing DTC with an alternative and supplemental source of default liquidity.

Terms of the Debt Issuance. DTC does not have immediate plans to initiate the Debt Issuance. The timing of a Debt Issuance would depend on a number of factors, including, for example, market conditions for the issuance of senior notes and the timing of any changes to DTC's liquidity needs. However, when it determines to do so it would engage a trustee and underwriting banks to issue the senior notes to qualified institutional investors through a private placement and offering in reliance on an exemption from registration under section 4(a)(2) of the Securities Act of 1933.[11] DTC would be party to certain transaction documents in connection with each issuance and private placement, including an indenture with the trustee and purchase agreements. The purchase agreements would each be based on the standard form of dealer agreement for similar debt issuances, which is published by the Securities Industry and Financial Markets Association.

While the anticipated material terms and conditions of a future Debt Issuance are summarized below, the actual terms of a future Debt Issuance would depend on a number of factors, including DTC's liquidity needs and the debt market conditions at the time of issuance. Therefore, with the exception of the authorized aggregate amount that DTC may issue of $5 billion, the anticipated terms summarized below are reasonable estimates, but may not reflect the actual terms of a future Debt Issuance.

DTC is proposing to issue up to an aggregate amount of $5 billion in senior notes, with an expected average amount issued and outstanding at any time of approximately $2–3 billion, as DTC deems reasonable, or as necessitated by liquidity needs. While, at the time of this filing, DTC would not need to issue up to the aggregate amount of $5 billion based on its current liquidity requirements, DTC believes that is advisable to authorize up to this aggregate amount in order to help manage its potential future liquidity needs and the potential risk that it is not able to obtain the requisite amounts from its other sources of default liquidity.

DTC estimates that each issuance would be in an amount between approximately $250 million and $1.5 billion, with an initial issuance expected to be between approximately $500 million and $1 billion.[12] DTC believes an initial issuance should be at an amount that would attract the attention of potential investors. Therefore, DTC believes that between approximately $500 million and $1 billion would be an appropriate amount for the initial issuance for this reason.

The senior notes would be represented by unsecured, unsubordinated and non-convertible medium-term and long-term global notes held in the name of DTC (as the central securities depository) or its nominee, Cede & Co. The notes would be issued and transferred only through the book-entry system of DTC. The senior notes would be interest bearing at either fixed or floating interest rates that are set at market rates customary for such type of debt and reflective of the creditworthiness of DTC.

DTC expects the average maturity of the senior notes issued under the Debt Issuance would be no shorter than approximately two years and no longer than approximately ten years, which are the typical lengths of medium-term and long-term debt. DTC does not believe maturities over ten years would be suitable as debt with longer maturities are generally more expensive to issue and may present higher risks related to interest rates. DTC would time each debt issuance and stagger maturity dates

issuance and private placement of senior notes, the Clearing Agencies would file a proposed rule change to amend the Framework to include the proceeds of the Debt Issuance as an additional qualifying liquidity resource of DTC.

[5] Capitalized terms not defined herein are defined in the Rules, By-Laws and Organization Certificate of DTC (''Rules'') available at *www.dtcc.com/~/media/Files/Downloads/legal/rules/dtc_rules.pdf. See also* Securities Exchange Act Release No. 80605 (May 5, 2017), 82 FR 21850 (May 10, 2017) (SR–DTC–2017–802; SR–NSCC–2017–802).

[6] In addition to default liquidity, DTC may use the proceeds of a Debt Issuance to prepay a prior Debt Issuance before maturity but would not use the proceeds for any other purpose. DTC filed as a confidential exhibit to this filing a sample term sheet that may be indicative of the possible terms of any future Debt Issuance.

[7] *Supra* note 4. Each of the Clearing Agencies is a wholly-owned subsidiary of The Depository Trust & Clearing Corporation, which operates on a shared service model with respect to the Clearing Agencies. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements under which it is generally DTCC that provides relevant services to the Clearing Agencies.

[8] *Id.*

[9] A description of the calculation of each Participant's Net Debit Cap and Collateral Monitor is available in the Settlement Service Guide. *See* DTC Settlement Service Guide, available at *www.dtcc.com/-/media/Files/Downloads/legal/service-guides/Settlement.pdf.*

[10] Under DTC Rule 10 (Discretionary Termination) and DTC Rule 11 (Mandatory Termination), a Participant will be in default if it fails to pay any amount due to DTC within specified timeframes, including the failure to fund a settlement obligation, to pay required deposits to the Participants Fund or to pay adequate assurances to DTC within the required timeframes. *See supra* note 5.

[11] 15 U.S.C. 77d(a)(2).

[12] If market conditions at the time of the inaugural issuance are favorable, DTC may issue an initial aggregate amount of more than $1 billion.

of each issuance in order to ladder the maturities. DTC would have the ability to make use of optional features to redeem the issued senior notes, in whole or in part, at any time prior to the maturity date of notes. More specifically, DTC would have the option to prepay any amount of principal owed on the issued senior notes before such payment is due, *i.e.,* before the maturity date.

DTC would hold the proceeds from the Debt Issuance in either its cash deposit account at the Federal Reserve Bank of New York (''FRBNY'') or in accounts at other creditworthy financial institutions in accordance with the Clearing Agency Investment Policy.[13] These amounts would be available to draw to complete settlement as needed.

DTC Liquidity Risk Management. DTC's liquidity needs for settlement are driven by protecting DTC against the possibility that a Participant may fail to pay its settlement obligations on a business day. The tools available to DTC under its Rules (*e.g.,* the Participants Fund, Net Debit Cap and Collateral Monitor) allow it to regularly test the sufficiency of liquid resources on an intraday and end-of-day basis and adjust to stressed circumstances during a settlement day to protect itself and Participants against liquidity exposure under normal and stressed market conditions.[14] DTC calculates its liquidity needs per Participant (at a legal entity level) and further aggregates these amounts at a family level (that is, including all affiliated Participants, based on the assumption that all such affiliates may fail simultaneously). In this regard, DTC monitors settlement flows and net-debit obligations on a daily basis, determines the appropriateness of each Participant's Net Debit Cap and monitors net settlement activity.

As noted above, the Framework describes DTC's liquidity risk management strategy, which is designed to maintain sufficient liquid resources to complete system-wide settlement on each business day, with a high degree of confidence and notwithstanding the failure to settle of the Participant, or affiliated family of Participants, with the largest settlement obligation.[15] The Framework also describes how DTC meets its requirement to hold qualifying liquid resources, as such term is defined in Rule 17Ad–22(a)(14) under the Securities Exchange Act of 1934 (''Act''),[16] sufficient to meet its minimum liquidity resource requirement in each relevant currency for which it has payment obligations owed to its Participants. DTC considers each of its existing default liquidity resources to be qualifying liquid resources, and the proceeds from the Debt Issuance would also be default liquidity that is considered a qualifying liquid resource.

The proceeds from the Debt Issuance would provide DTC with additional, prefunded, and readily available qualifying liquid resources to be used to complete system-wide settlement if a Participant defaults. For DTC, the Participants Fund, Net Debit Cap and Collateral Monitor tools work together to limit potential liquidity requirements in default scenarios both on an intra-day and end-of-day basis. So, while DTC's current available liquidity resources are sufficient to satisfy the single-largest family default under stressed but plausible conditions, the Debt Issuance would allow DTC to diversify its sources of default liquidity and mitigate risks to DTC that it is unable to secure default liquidity resources in an amount necessary to meet its liquidity needs. More specifically, the proposal would provide DTC with the flexibility to reduce its reliance on the Line of Credit, which is renewed annually and dependent on continued lender interest and meet any increased liquidity needs it may face in the future. As a source of prefunded, default liquidity, the Debt Issuance would provide additional certainty, stability, and safety to DTC, its Participants, and the U.S. markets that it serves.

By diversifying DTC's sources of qualifying liquid resources, the Debt Issuance could also mitigate concentration risks related to its liquidity providers. More specifically, while DTC would not limit the potential qualified institutional investors that purchase senior notes and, therefore, is not able to ensure that the Debt Issuance would reduce concentration risk, the types of entities who typically invest in senior notes (for example, insurance companies, asset managers and pension funds) are generally not Participants of DTC or lenders under the Line of Credit. Therefore, the prospective investors in the senior notes are not expected to be the same firms that currently provide any material amount of default liquidity resources to DTC either through the Line of Credit, or as DTC Participants. In this way, the proposed Debt Issuance would reduce the concentration risk related to its liquidity providers, by reducing the likelihood that an impairment of a liquidity provider to perform under one qualifying liquid resource would impact DTC's ability to fully access its other qualifying liquid resources.

Anticipated Effect on and Management of Risk

In connection with its role as a central securities depository (''CSD''), DTC provides for both the settlement of book-entry transfer and pledge of interests in eligible deposited securities and net funds settlement. A financially strong and well-managed, well-designed CSD, with appropriate risk management arrangements, can reduce the risk faced by participants, contributing to the goal of systemic financial stability. In order to sufficiently perform this role, it is critical that DTC has access to adequate liquidity resources to enable it to complete system-wide settlement every business day, including following a Participant default. DTC believes that the overall impact of the proposed Debt Issuance on risks presented by DTC would be to reduce the liquidity risks associated with DTC's net settlement obligations by providing it with an additional source of liquidity to complete system-wide settlement in the event of a Participant default. DTC further believes that a reduction in its liquidity risk would reduce systemic risk and would have a positive impact on the safety and soundness of the wider financial system.

While the proposed Debt Issuance, like any liquidity resource, would involve certain risks, most of these risks are standard in any debt issuance. One risk associated with the proposed Debt Issuance would be the risk that DTC does not have sufficient funds to repay issued senior notes when the notes mature. DTC believes that this risk is extremely remote, as the proceeds of the Debt Issuance would be used only in the event of a Participant default, and DTC would replenish that cash, as it would replenish any of its liquidity resources that are used to facilitate settlement in the event of a Participant default, with the proceeds of the close out of that defaulted Participant's portfolio. This notwithstanding, in the event that proceeds from the close out are

[13] *See* Securities Exchange Act Release Nos. 79528 (Dec. 12, 2016), 81 FR 91232 (Dec. 16, 2016) (SR–DTC–2016–007, SR–FICC–2016–005, SR–NSCC–2016–003); 84949 (Dec. 21, 2018), 83 FR 67779 (Dec. 31, 2018) (SR–DTC–2018–012, SR–FICC–2018–014, SR–NSCC–2018–013). Following the issuance of a Notice of No Objection by the Commission of this proposal, the Clearing Agencies would file a proposed rule change to amend the Clearing Agency Investment Policy to include the proceeds as default liquidity funds, within the definition of ''Investable Funds,'' as such term is defined therein, and provide that such amounts would be held in bank deposits at eligible commercial banks or at DTC's cash deposit account at the FRBNY.

[14] *Supra* note 4.

[15] *Supra* note 5.

[16] 17 CFR 240.17Ad–22(a)(14).

insufficient to fully repay a liquidity borrowing, then DTC would look to its loss waterfall to repay any outstanding liquidity borrowings.[17] DTC would further mitigate this risk through the timing of each debt issuance and by staggering the maturity dates of the issued senior notes in a way that would provide DTC with time to complete the close out of a defaulted Participant's portfolio. A second risk is that DTC may be unable to issue new senior notes as issued notes mature due to, for example, stressed markets at the time the issued debt matures. This risk is mitigated by the fact that DTC maintains a number of different default liquidity resources, described above, and would not depend on the Debt Issuance as its sole source of liquidity.

DTC may be exposed to interest rate risk, which is the risk that a change in interest rates could cause an increase to the net cost of carry of the Debt Issuance.[18] DTC would mitigate this risk by issuing senior notes at different maturities and at both fixed interest rates and floating interest rates. The interest rates for the senior notes issued at floating interest rates would generally correlate with the rates on investments of those proceeds [19] and would be expected to result in a largely stable net spread between the borrowing interest rate and the investment interest rate, mitigating this risk. For the senior notes issued with a fixed interest rate, DTC would consider interest rate swaps as a method to mitigate interest rate risk, depending on market environment at that time.

DTC could also face a related financial risk that the expense of a Debt Issuance exceeds DTC's income and may have a negative impact on DTC's financial health or its creditworthiness. DTC would mitigate this risk by evaluating the expected net cost of carry (discussed above) of a Debt Issuance prior to issuing any debt, and if the financing costs for the issuance of senior notes increase, such that it is not financially advisable to issue additional senior notes, then DTC may determine to use its alternative liquidity resources to meet its liquidity needs during those market conditions.

DTC believes that the significant systemic risk mitigation benefits of providing DTC with additional, prefunded liquidity resources outweigh these risks.

Consistency With Clearing Supervision Act

DTC believes that that proposal would be consistent with Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act''), specifically with the risk management objectives and principles of section 802(b)(1), and with certain of the risk management standards adopted by the Commission pursuant to section 805(a)(2), for the reasons described below.[20]

(i) Consistency With Section 805(b)(1) of the Clearing Supervision Act

Although the Clearing Supervision Act does not specify a standard of review for an advance notice, its stated purpose is instructive: to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[21]

DTC believes the proposal is consistent with section 805(b)(1) of the Clearing Supervision Act because it would support the mitigation of systemic risk in the financial system and promote financial stability in the event of a Participant default by strengthening DTC's liquidity. The proposed Debt Issuance is designed to reduce DTC's liquidity risks by providing it with an additional source of liquidity to complete system-wide settlement in the event of a Participant default. By supplementing DTC's existing default liquidity resources with prefunded liquidity, the proposal would contribute to DTC's goal of assuring that DTC has adequate liquidity resources to meet its settlement obligations notwithstanding the default of any of its Participants.

In its critical role as a CSD, DTC provides for both the settlement of book-entry transfer and pledge of interests in eligible deposited securities and net funds settlement. In order to sufficiently perform this role, it is critical that DTC has access to adequate liquidity resources to enable it to complete system-wide settlement every business day, including following a Participant default. Therefore, a reduction in DTC's liquidity risk would reduce systemic risk and would have a positive impact on the safety and soundness of the wider financial system.

As a result, DTC believes the proposed Debt Issuance would be consistent with the objectives and principles of section 805(b)(1) of the Clearing Supervision Act, which specify the promotion of robust risk management, promotion of safety and soundness, reduction of systemic risks and support of the stability of the broader financial system by, among other things, strengthening the liquidity of systemically important financial market utilities, such as DTC.

(ii) Consistency With Rule 17Ad–22(e)(7)(i) and (ii) Under the Act

Section 805(a)(2) of the Clearing Supervision Act authorizes the Commission to prescribe risk management standards for the payment, clearing and settlement activities of designated clearing entities, like DTC, and financial institutions engaged in designated activities for which the Commission is the supervisory agency or the appropriate financial regulator.[22] The Commission has accordingly adopted risk management standards under section 805(a)(2) of the Clearing Supervision Act [23] and section 17A of the Act (''Covered Clearing Agency Standards'').[24] The Covered Clearing Agency Standards require covered clearing agencies to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.[25]

DTC believes that the proposed Debt Issuance is consistent with Rule 17Ad–22(e)(7)(i) and (ii) of the Covered Clearing Agency Standards for the reasons described below.[26]

Rule 17Ad–22(e)(7)(i) under the Act requires that DTC establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain sufficient liquid resources at the minimum in all relevant currencies to effect same-day and, where appropriate, intraday and multiday settlement of payment obligations with a high degree of confidence under a wide range of foreseeable stress scenarios that includes, but is not limited to, the default of the participant family that would generate the largest aggregate payment obligation for the covered clearing agency in extreme but plausible market conditions.[27] Rule

[17] *See* Rule 4 (Participants Fund and Participants Investment) of the Rules, *supra* note 5.

[18] The ''net cost of carry'' generally refers to the difference between the interest earned on the invested proceeds of an issuance and the interest rate paid on that issuance.

[19] *See supra* note 12.

[20] 12 U.S.C. 5464(a)(2) and (b)(1).

[21] 12 U.S.C. 5464(b)(1).

[22] 12 U.S.C. 5464(a)(2).

[23] *Id.*

[24] 17 CFR 240.17Ad–22(e).

[25] *Id.*

[26] 17 CFR 240.17Ad–22(e)(7)(i), (ii).

[27] 17 CFR 240.17Ad–22(e)(7)(i).

17Ad–22(e)(7)(ii) under the Act requires that DTC establish, implement, maintain and enforce written policies and procedures reasonably designed to hold qualifying liquid resources sufficient to meet the minimum liquidity resource requirement under Rule 17Ad–22(e)(7)(i) in each relevant currency for which DTC has payment obligations owed to its Participants.[28]

As described above, the proposed Debt Issuance would provide DTC with an additional resource of prefunded default liquidity, which it would use to complete system-wide settlement every business day, including following a Participant default. The proceeds of the Debt Issuance would be cash held by DTC at either its cash deposit account at the FRBNY or at a creditworthy commercial bank, pursuant to the Clearing Agency Investment Policy.[29] Therefore, the proceeds of the Debt Issuance would be considered a qualifying liquid resource, as defined by Rule 17Ad–22(a)(14).[30] As such, the proposed Debt Issuance would support DTC's ability to hold sufficient qualifying liquid resources to meet its minimum liquidity resource requirement under Rule 17Ad–22(e)(7)(i).[31]

For these reasons, DTC believes the proposal would support DTC's compliance with Rule 17Ad–22(e)(7)(i) and (ii) by providing it with an additional qualifying liquid resource.[32]

III. Date of Effectiveness of the Advance Notice, and Timing for Commission Action

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date that the proposed change was filed with the Commission or (ii) the date that any additional information requested by the Commission is received. The clearing agency shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date the advance notice is filed, or the date further information requested by the Commission is received, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

The clearing agency shall post notice on its website of proposed changes that are implemented.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the Advance Notice is consistent with the Clearing Supervision 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–DTC–2023–801 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR–DTC–2023–801. 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 Advance Notice that are filed with the Commission, and all written communications relating to the Advance Notice 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 DTC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*).

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–DTC–2023–801 and should be submitted on or before September 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–18776 Filed 8–30–23; 8:45 am]

BILLING CODE 8011–01–P

[28] 17 CFR 240.17Ad–22(e)(7)(ii). For purposes of this Rule, ''qualifying liquid resources'' are defined in Rule 17Ad–22(a)(14) as including, in part, cash held either at the central bank of issue or at creditworthy commercial banks. 17 CFR 240.17Ad–22(a)(14).

[29] *Supra* note 13.

[30] 17 CFR 240.17Ad–22(a)(14).

[31] 17 CFR 240.17Ad–22(e)(7)(i).

[32] 17 CFR 240.17Ad–22(e)(7)(i), (ii).

[33] 17 CFR 200.30–3(a)(91).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98225; File No. SR–NASDAQ–2023–030]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule To Delay Implementation of Pending Amendments to Equity 4, Rules 4120, 4702 and 4703 and To Make Further Amendments to Rules 4702 and 4703

August 25, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 16, 2023, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The 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 delay implementation of pending amendments to Equity 4, Rules 4120, 4702 and 4703 [3] as well as to make further amendments to Rules 4702 and 4703, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] References herein to Nasdaq Rules in the 4000 Series shall mean Rules in Nasdaq Equity 4.

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 Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is in the process of introducing a new upgraded version of the OUCH Order entry protocol [4] that will, when fully implemented, enable the Exchange to make functional improvements to specific Order Types [5] and Order Attributes.[6] The Exchange filed its initial proposal (the ''Proposal'') for these enhancements with the SEC on September 14, 2022, and in the Proposal the Exchange stated that its operative date would be November 14, 2022.[7] The Exchange subsequently informed the Commission that it intended to delay implementation of the migration due to ongoing development work.[8] The Exchange now wishes to inform participants that while it has commenced and systematically affected migration on a feature-by-feature basis, as described in a series of Equity Trader Alerts,[9] the migration will not be complete until Q1 2024—again, due to ongoing development work. Until the migration is complete, the Exchange will continue to announce the implementation dates for the remaining new OUCH functionalities, in Equity Trader Alerts at least 30 days prior to implementation.

Additionally, the Exchange also proposes amendments to its Rules to address inconsistencies between the Rule Text and observed System behavior as well as behavior unaccounted for in the existing and pending Rule text, as follows.

First Rule Change

The first proposed rule change addresses an edge case of inconsistency between the Rule text and System behavior, this time regarding Market Maker Peg Orders.[10] Rule 4702(b)(7)(A) states that, if after entry of a Market Maker Peg Order that has a displayed price based on the NBBO, and the NBBO subsequently shifts such that the displayed price of the Market Maker Peg Order to buy (sell) is equal to or greater (less) than the National Best Bid (or National Best Offer), the Market Maker Peg Order will not be subsequently repriced until a new reference price is established that is more aggressive than the displayed price of the Market Maker Peg Order. System testing revealed that the System does not reprice Market Maker Peg Orders in this scenario, but only if such Orders are in round lot sizes, whereas it does reprice such Orders when they are in odd lot sizes. After evaluation, the Exchange determined to maintain this System behavior and amend the Rule to conform to it. The Exchange proposes to do so because the existing language proscribing repricing only makes sense within the context of round lot Market Maker Peg Orders, which this scenario would set a new NBBO and when they do so, cannot reprice with respect to the reference price they just set. By contrast, odd lot Market Maker Peg Orders are ineligible to set the NBBO, and do not have this same problem. Accordingly, the Exchange proposes to amend Rule 4702(b)(7)(A) to clarify that the prohibition against repricing only applies to Market Maker Peg Orders in odd lot sizes.

Second Rule Change

The second proposed amendment addresses how the System prices a Market on Open Order [11] with the Market Pegging Attribute [12] and an offset assigned to it that a participant enters after the Nasdaq Opening Cross occurs. Rule 4702(b)(8)(B) currently provides as follows with respect to this scenario:

An MOO Order entered through RASH or FIX with a Time-in-Force of IOC and flagged to participate in the Nasdaq Opening Cross that is entered after the time of the Nasdaq Opening Cross will be accepted but will be converted into a Non-Displayed Order with a Time-in-Force of IOC and a price established using the Market Pegging Order Attribute with no offset.[13]

In testing System behavior, the Exchange observed that the System does not, in fact, operate in this manner Instead, the System determines the price

[4] The OUCH Order entry protocol is a proprietary protocol that allows subscribers to quickly enter orders into the System and receive executions. OUCH accepts limit Orders from members, and if there are matching Orders, they will execute. Non-matching Orders are added to the Limit Order Book, a database of available limit Orders, where they are matched in price-time priority. OUCH only provides a method for members to send Orders and receive status updates on those Orders. See *https://www.nasdaqtrader.com/Trader.aspx?id=OUCH.*

[5] An ''Order Type'' is a standardized set of instructions associated with an Order that define how it will behave with respect to pricing, execution, and/or posting to the Exchange Book when submitted to Nasdaq. *See* Equity 1, Section 1(a)(7).

[6] An ''Order Attribute'' is a further set of variable instructions that may be associated with an Order to further define how it will behave with respect to pricing, execution, and/or posting to the Exchange Book when submitted to the Exchange. *See id.*

[7] *See* Securities Exchange Act Release No. 34–95768 (September 14, 2022); 87 FR 57534 (September 20, 2022) (SR–Nasdaq–2022–051).

[8] *See* Securities Exchange Act Release No. 34–96341 (November 17, 2022), 87 FR 71712 (November 22, 2022) (SR–Nasdaq–2022–065).

[9] *See* Equity Trader Alert 2023–35 (August 2, 2023) (announcing implementation of Midpoint Peg Order functionality), available at *http://www.nasdaqtrader.com/TraderNews.aspx?id=ETA2023-35;* Equity Trader Alert 2023–28 (June 22, 2023) (announcing implementation of Market Peg functionality), available at *http://www.nasdaqtrader.com/TraderNews.aspx?id=ETA2023-28;* Equity Trader Alert 2023–20 (May 9, 2023) (announcing implementation of Primary Peg order functionality), available at *http://www.nasdaqtrader.com/TraderNews.aspx?id=ETA2023-20;* Equity Trader Alert 2023–17 (April 27, 2023) (announcing implementation of Reserve Order functionality), available at *http://www.nasdaqtrader.com/TraderNews.aspx?id=ETA2023-17;* Equity Trader Alert 2023–6 (January 31, 2023) (announcing implementation of Trade Now functionality); Equity Trader Alert 2022–96 (October 26, 2022) (announcing implementation delay until Q2/Q3 2023), available at *http://www.nasdaqtrader.com/TraderNews.aspx?id=%20ETA2022-96.*

[10] Pursuant to Rule 4702(b)(7)(A), a ''Market Maker Peg Order'' is an Order Type designed to allow a Market Maker to maintain a continuous two-sided quotation at a displayed price that is compliant with the quotation requirements for Market Makers set forth in Equity 2, Section 5(a)(2). The displayed price of the Market Maker Peg Order is set with reference to a ''Reference Price'' in order to keep the displayed price of the Market Maker Peg Order within a bounded price range. The Reference Price for a Market Maker Peg Order to buy (sell) is the then-current National Best Bid (National Best Offer) (including Nasdaq), or if no such National Best Bid or National Best Offer, the most recent reported last-sale eligible trade from the responsible single plan processor for that day, or if none, the previous closing price of the security as adjusted to reflect any corporate actions (*e.g.,* dividends or stock splits) in the security.

[11] *See* Rule 4702(b)(8) (defining a ''Market on Open Order'' or ''MOO'' as follows: ''an Order Type entered without a price that may be executed only during the Nasdaq Opening Cross. Subject to the qualifications provided below, MOO Orders may be entered between 4 a.m. ET and immediately prior to 9:28 a.m. ET. An MOO Order may be cancelled or modified until immediately prior to 9:25 a.m. ET. An MOO Order shall execute only at the price determined by the Nasdaq Opening Cross.'').

[12] *See* Rule 4703(d)(8) (defining ''market pegging'' as pegging ''with reference to the Inside Quotation on the opposite side of the market.'').

[13] A Time-in-Force or ''TIF'' is a period of time that the Exchange will hold an Order for potential execution. *See* Rule 4703(a). An Order with a TIF of Immediate-or-Cancel or ''IOC'' is designated to deactivate immediately after determining whether it is marketable. *See id.*

of the Order in this scenario using the offset. In evaluating whether to modify System behavior to match the Rule, the Exchange determined to retain the current System behavior because it did not see any reasonable basis to ignore the offset in this scenario. The Exchange proposes to amend the Rule accordingly.

Third Rule Change

The third proposed rule change regards an Order with the Pegging Attribute that a participant: (1) enters before the Nasdaq Closing Cross occurs at 4:00 p.m.; and (2) assigns a TIF which designates the Order for extended hours trading if it remains unexecuted after the Cross concludes (while bypassing the Extended Trading Close). Under the Rule, as amended by SR–Nasdaq–2022–051, such an Order would be booked into the System, but if it remains unexecuted after the Nasdaq Closing Cross concludes, the Order would remain booked and commence extended hours trading, but the System would deactivate its Pegging Attribute when doing so. In other words, the Order would cease managing the pegged price of the Order after 4 p.m. This practice is consistent with Equity 4, Rule 4703(d), which states that ''Pegging is available only during Market Hours.''

The Exchange now proposes to amend Rule 4703(d) to state that if a participant enters a Peg Managed Order [14] prior to the Nasdaq Closing Cross with a TIF that allows for extend hours trading (other than in the Extended Trading Close), the System will cancel that Order if unexecuted after the Nasdaq Closing Cross concludes. By contrast, if a participant enters a Fixed Midpoint Order [15] in the same scenario, the System will act as it does now—it will deactivate the Pegging Attribute for the Order once extend hours trading commences.

In time, the proposed treatment of Peg Managed Orders during extended hours trading is that which the Exchange intends to apply to all Midpoint Pegging Orders. However, this functionality is not yet ready to make it available for Fixed Midpoint Orders. Thus, in the interim, existing practice will continue.

Fourth Rule Change

The fourth proposal would amend Equity 4, Rule 4703(h), to correct its description of behavior of the Non-Displayed portion of Orders with the Reserve Attribute.[16] As amended by SR–Nasdaq–2022–051, Rule 4703(h) provides as follows, in pertinent part:

In all cases, if the remaining size of the Non-Displayed Order is less than the fixed or random amount stipulated by the Participant, the full remaining size of the Non-Displayed Order will be displayed and the Non-Displayed Order will be removed.

As stated, this Rule requires that the entire Non-Displayed portion of a Reserve Order will become Displayed the moment the size of the Non-Displayed portion [17] drops below an amount that a participant designates or has directed the System to randomly designate (the ''Max Floor''). In conducting a test of System behavior, however, the Exchange observed that the System does not, in fact, operate in this manner. Instead, the System maintains the Non-Displayed portion of a Reserve Order as such when the size of that Non-Displayed Portion drops below the Max Floor. Rather than correct the current System behavior to match the Rule, the Exchange determined that users of Reserve Orders prefer the current System behavior because it is true to the underlying intent of Reserve functionality, which is to help limit the price impacts of trading large quantities of shares by displaying only small portions of such shares at a given time, while hiding the rest in reserve. Thus, the Exchange proposes to address the inconsistency between the Rule text and the behavior of the System by deleting the aforementioned language from Rule 4703(d) [sic]. Going forward, the System will not convert to a Displayed Order the Non-Displayed remainder of a Reserve Order that falls below the Max Floor, and the System will not remove it.

2. Statutory Basis

The Exchange believes that its proposals are consistent with Section 6(b) of the Act,[18] in general, and further the objectives of Section 6(b)(5) of the Act,[19] in particular, in that they are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

It is consistent with the Act and in the best interests of investors and the public to announce a delay in its completion of implementing the amendments to the Exchange's Rulebook set forth in SR–Nasdaq–2022–051. Doing so will avoid confusion as to which rules and functionality will apply during the interim period. As noted earlier, the Exchange has and will continue to notify market participants through Equity Trader Alerts in advance of implementing any new functionality set forth in SR–Nasdaq–2022–051.

It is also consistent with the Act to amend the Exchange's Rules to address inconsistencies between the Rule text and observed System behavior, including by adapting the Rule text to codify observed System behavior, where the observed behavior is more consistent with the underlying purpose of an Order Attribute than is the Rule text (maintaining the Non-Displayed status of a reserve portion of a Reserve Order that drops below the Max Floor), where the Exchange discerns no logical reason to maintain the existing Rule text (ignoring an offset assigned to MOOs with Market Pegging entered after the Nasdaq Opening Cross occurs), and where System behavior reflects a nuance not contemplated by the existing Rules (clarifying that the prohibition against repricing Market Maker Peg Orders that have prices equal to or better than the NBBO only applies to round lot Market Maker Peg Orders, and not to odd lots).

Likewise, it is consistent with the Act to amend the Exchange's Rules to provide for the System to cancel Managed Peg Orders designated for extended hours trading, when such Orders remain unexecuted in the

[14] A ''Peg Managed Order'' is a Primary Pegged, Market Pegged, or Managed Midpoint Order. *See* 4703(d) (as amended by SR–Nasdaq–2022–051). A ''Managed Midpoint Order,'' in turn, is a Midpoint Pegging Order which the System may update in response to changes to the Midpoint. *See id.*

[15] A ''Fixed Midpoint Order'' is a Midpoint Pegging Order which the System will cancel in response to changes to the Midpoint. *See id.*

[16] ''Reserve Size'' is, in part, an Order Attribute that ''permits a Participant to stipulate that an Order Type that is displayed may have its displayed size replenished from additional non-displayed size.'' Rule 4703(h). The Rule also states that Reserve ''is not available for Orders that are not displayed; provided, however, that if a Participant enters Reserve Size for a Non-Displayed Order with a Time-in-Force of IOC, the full size of the Order, including Reserve Size, will be processed as a Non-Displayed Order.'' *Id.* In addition to the change proposed above, the Exchange proposes to eliminate from the immediately preceding language ''with a Time-in-Force of IOC'' because the Exchange does not assess a reason to include this qualifier. The statement that a Non-Displayed Order with Reserve will be entirely non-displayed is true even as to Non-Displayed Orders with other TIFs.

[17] Whenever a participant enters an Order with Reserve Size, the full size of the Order will be presented for potential execution in compliance with Regulation NMS; thereafter, unexecuted portions of the Order will be processed as two Orders: a Displayed Order (with the characteristics of its selected Order Type) and a Non-Displayed Order. *See id.* When an Order with Reserve Size is posted, if there is an execution against the Displayed Order that causes its size to decrease below a normal unit of trading, another Displayed Order will be entered at the limit price and size stipulated by the Participant while the size of the Non-Displayed Order will be reduced by the same amount. *See id.*

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

Nasdaq Closing Cross, due to the fact that the Rule text provides that pegging is only available during market hours. It is also consistent with the Act to maintain its existing practice for Fixed Midpoint Orders, in the same scenario, of deactivating the Pegging Attribute during extended hours trading. Although the proposal will create disparate treatment of Managed Peg Orders and Fixed Midpoint Orders, the Exchange intends to eliminate this disparity over time by providing for Fixed Midpoint Orders to behave in the same way as Managed Peg Orders. Until that occurs, maintaining existing practice for Fixed Midpoint Orders is consistent with the Rule.

Finally, it is consistent with the Act to amend Rule 4703(h) to delete qualifying language which erroneously suggests that Non-Displayed Orders with Reserve are only non-displayed when such Orders have a TIF of IOC. Investors and the public have an interest in the Exchange maintaining a Rulebook that is accurate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposals merely delay completion of its implementation of SR–Nasdaq–2022–051 as well as address inconsistencies between Rule text and System behavior that became apparent during the course of this implementation. The Exchange neither intends nor perceives that these rule changes will have any impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [20] and Rule 19b–4(f)(6) thereunder.[21] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [22] and Rule 19b–4(f)(6)(iii) thereunder.[23]

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) [24] 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–NASDAQ–2023–030 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2023–030. 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–NASDAQ–2023–030 and should be submitted on or before September 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–18777 Filed 8–30–23; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(3)(A)(iii).

[21] 17 CFR 240.19b–4(f)(6).

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[24] 15 U.S.C. 78s(b)(2)(B).

[25] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #18022 and #18023; Oklahoma Disaster Number OK–00171]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Oklahoma

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Oklahoma (FEMA–4721–DR), dated 07/19/2023.

Incident: Severe Storms, Straight-line Winds, and Tornadoes.

Incident Period: 06/14/2023 through 06/18/2023.

DATES: Issued on 08/15/2023.

Physical Loan Application Deadline Date: 09/18/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 04/19/2024.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and

Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Oklahoma, dated 07/19/2023, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Atoka, McIntosh, Muskogee, Wagoner

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2023–18804 Filed 8–30–23; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #18109; Rhode Island Disaster Number RI–00027 Declaration of Economic Injury]

Administrative Declaration of an Economic Injury Disaster for the State of Rhode Island

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of Rhode Island dated 08/25/2023.

Incident: Block Island Hotel Fire.

Incident Period: 08/18/2023.

DATES: Issued on 08/25/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 05/28/2024.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:
Washington

Contiguous Counties:
Rhode Island: Kent, Newport
Connecticut: New London

The Interest Rates are:

	Percent
Businesses and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	2.375

The number assigned to this disaster for economic injury is 181090.

The States which received an EIDL Declaration #18109 are Rhode Island, Connecticut.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2023–18810 Filed 8–30–23; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #18094 and #18095; Hawaii Disaster Number HI–00074]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Hawaii

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Hawaii (FEMA–4724–DR), dated 08/21/2023.

Incident: Wildfires.

Incident Period: 08/08/2023 and continuing.

DATES: Issued on 08/21/2023.

Physical Loan Application Deadline Date: 10/20/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 05/21/2024.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 08/21/2023, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Maui

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.375

The number assigned to this disaster for physical damage is 18094 5 and for economic injury is 18095 0.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2023–18803 Filed 8–30–23; 8:45 am]

BILLING CODE 8026–09–P

STATE JUSTICE INSTITUTE

SJI Board of Directors Meeting, Notice

AGENCY: State Justice Institute.

ACTION: Notice of meeting.

SUMMARY: The purpose of this meeting is to consider grant applications for the 4th quarter of FY 2023, and other business.

DATES: The SJI Board of Directors will be meeting on Monday, September 18, 2023 at 1:00 p.m. CT.

ADDRESSES: Kansas Judicial Center, 301 SW 10th Avenue First Floor Conference Room, Topeka, Kansas.

FOR FURTHER INFORMATION CONTACT: Jonathan Mattiello, Executive Director, State Justice Institute, 12700 Fair Lakes Circle, Suite 340, Fairfax, VA 22033, 703–660–4979, *contact@sji.gov.*

(Authority: 42 U.S.C. 10702(f))

Jonathan D. Mattiello,

Executive Director.

[FR Doc. 2023–18873 Filed 8–30–23; 8:45 am]

BILLING CODE 6820–SC–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36718]

East Chattanooga Belt Railway Company, LLC—Acquisition and Operation Exemption—Norfolk Southern Railway Company

East Chattanooga Belt Railway Company, LLC (ECTB), a Class III carrier, has filed a verified notice of exemption under 49 CFR 1150.41, to lease from Norfolk Southern Railway Company (NSR) and to operate approximately 0.24 miles of rail line extending between milepost C448 in the vicinity of CP 23rd Street and milepost C447.7, a point roughly 100 feet south of the southernmost bridge abutment of a bridge over Dobbs Branch, also known as Spring Branch (the Line).[1]

According to ECTB, it has reached an agreement with NSR to supplement the terms of an original lease between them, dated April 1, 2001.[2] ECTB states that the supplemental agreement expands its leasehold interest by extending to it the right to operate over and the obligation to maintain the Line, which is proximate to a line that ECTB currently operates pursuant to the original lease agreement. According to ECTB, it will obtain the right to conduct overhead operations over the Line and NSR will retain the obligation to provide local service on the Line in the event any such service demand emerges.

ECTB certifies that its anticipated annual freight common carrier revenues following consummation of the proposed transaction will qualify it as a Class III carrier and will not exceed $5 million. ECTB also certifies that the agreements do not contain any provision that would limit ECTB's ability to interchange traffic with any third-party connecting carrier.

The transaction may be consummated on or after September 14, 2023, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than September 7, 2023 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36718, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on ECTB's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3268.

According to ECTB, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: August 28, 2023.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2023–18861 Filed 8–30–23; 8:45 am]

BILLING CODE 4915–01–P

[1] ECTB notes that, mileposts notwithstanding, the distance between the terminal points of the lease has been calculated to be approximately 1,250 feet, which equates to 0.24 miles, not 0.3 miles.

[2] *See E. Chattanooga Belt Ry.—Acquis. & Operation Exemption—Norfolk S. Ry.,* FD 34024 (STB served Apr. 10, 2001).

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2023–0026]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for an information collection, which is summarized below under Supplementary Information. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by October 2, 2023.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 0026 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Spencer Stevens, 202–366–6221, Office of Planning, Environment and Realty Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Title: Planning and Research Program Administration

Background: Planning and Research Program Administration is covered under 23 CFR part 420. 23 CFR part 420 regulation includes administrative requirements and procedures for PL funds (23 U.S.C. 104(b)(5)) provided for Metropolitan Planning Organizations (MPOs) to carry out metropolitan planning, and SPR funds (provided under the provisions of 23 U.S.C. 505) for State Departments of Transportation (State DOTs) to implement statewide transportation planning and research, development and technology (RD&T) work activities. Also, at a State DOT's option, other title 23 funds as identified in the definition of FHWA planning and research funds in 23 U.S.C. 505 and 23 CFR 420.103 may be used to perform planning activities. Different from this request, the information collection requirement for work performed by MPOs is a joint Federal Highway Administration/Federal Transit Administration requirement, and is covered under OMB Control Number 2132–0529.

In accordance with government-wide grant management procedures, a grant application must be submitted for these funds. In addition, recipients must submit periodic progress and financial reports. The content and frequency of submission of progress and financial reports specified in 23 CFR part 420 is as specified in 2 CFR 200 grant management regulations. With the implementation of 2 CFR 200, the focus will be more on using data to determine the grant's achievement outcomes and less on accountability compliance. FHWA and the State DOTs are called upon to identify clear performance goals, indicators and milestones for the grants.

This information collection supports the DOT's Strategic Objective of ''Organizational Excellence'' by providing an ongoing mechanism to review applications and approve Federal grants to States for their

transportation planning and research, development and technology work programs.

Respondents: Each State, the District of Columbia and the Commonwealth of Puerto Rico are required to provide information. The annual number of burden hours (professional and clerical staff) per respondent for preparation of work programs and progress and financial reports is estimated to be 720 (18 weeks × 40 hours per week). The total annual burden for all respondents is estimated to be 37,440 burden hours (720 burden hours per respondent times 52 respondents).

Frequency: This annual burden consists of staff time of each respondent for preparation of the work programs, and progress and financial reports. For those respondents that elect to use biennial work programs, the burden for preparation of work programs would be significantly less for the second year.

Estimated Average Burden per Response: Professional staff time for preparation of work programs: 400 hours/respondent. Professional staff time for preparation of progress and financial reports: 120 hours/respondent Clerical staff time: 200 hours/respondent.

Estimated Total Annual Burden Hours: 720 hours/respondent × 52 respondents = 37,400 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, 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.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: August 28, 2023.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2023–18838 Filed 8–30–23; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Limitation on Claims Against Proposed Public Transportation Project—Honolulu Rail Transit Project Modifications

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice announces final environmental actions taken by the Federal Transit Administration (FTA) regarding the Honolulu Rail Transit Project, City of Honolulu, Honolulu County, Hawaii. The purpose of this notice is to publicly announce FTA's environmental decisions on the subject project, and to activate the limitation on any claims that may challenge these final environmental actions.

DATES: A claim seeking judicial review of FTA actions announced herein for the listed public transportation project will be barred unless the claim is filed on or before January 29, 2024.

FOR FURTHER INFORMATION CONTACT: Kathryn Loster, Assistant Chief Counsel, Office of Chief Counsel, (312) 705–1269, or Saadat Khan, Environmental Protection Specialist, Office of Environmental Programs, (202) 366–9647. FTA is located at 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 9:00 a.m. to 5:00 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FTA has taken final agency actions subject to 23 U.S.C. 139(l) by issuing certain approvals for the public transportation project listed below. The actions on the project, as well as the laws under which such actions were taken, are described in the documentation issued in connection with the project to comply with the National Environmental Policy Act (NEPA) and in other documents in the FTA environmental project files for the project. Interested parties may contact either the project sponsor or the relevant FTA Regional Office for more information. Contact information for FTA's Regional Offices may be found at *https://www.transit.dot.gov.*

This notice applies to all FTA decisions on the listed project as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to, NEPA (42 U.S.C. 4321–4375), Section 4(f) requirements (49 U.S.C. 303), Section 106 of the National Historic Preservation Act (54 U.S.C. 306108), Uniform Relocation and Real Property Acquisition Policies Act (42 U.S.C. 4601). This notice does not, however, alter or extend the limitation period for challenges of project decisions subject to previous notices published in the **Federal Register**. The project modifications and actions that are the subject of this notice follow:

Project name and location: Honolulu Rail Transit Project (Project), City of Honolulu, Honolulu County, Hawaii. *Project Sponsor:* Honolulu Authority for Rapid Transportation (HART), Honolulu, Hawaii. *Project description:* The Project is a 20-mile, automated fixed-guideway rail system with 21 stations extending from East Kapolei to Ala Moana Transit. The Project is separated into three phases, two of which have been constructed. FTA issued the Honolulu High-Capacity Transit Corridor Project Final Environmental Impact Statement/Section 4(f) Evaluation in June 2010, and a Record of Decision (ROD) in January 2011. Subsequent to the original ROD, FTA issued the Honolulu High-Capacity Transit Corridor Project Final Supplemental Environmental Impact Statement (FSEIS)/Section 4(f) Evaluation and amended ROD in September 2013. FTA also published a notice of limitation on claims against the Project on November 1, 2013, per 23 U.S.C. 139(l). Since then, FTA has completed a re-evaluation of the Project to address changes that have been proposed by HART resulting from design modifications (*e.g.,* reducing the number of stations to 19), temporary reduction in the length of the Project from 20 miles to 18.9 miles, and stakeholder coordination. This notice only applies to the discrete actions taken by FTA under the re-evaluation described below.

Final agency actions: FTA determined as the result of the re-evaluation that neither a Supplemental Environmental Impact Statement nor a Supplemental Environmental Assessment is necessary, and the 2011 ROD, and September 2013 FSEIS and amended ROD remain valid.

Supporting documentation: Environmental Re-evaluation concerning the Project modifications dated August 24, 2023. All supporting documentation can be viewed and downloaded from: *https://www.transit.dot.gov/regulations-and-guidance/environmental-programs/environmental-decision-documents.*

Authority: 23 U.S.C. 139(l)(1).

Mark Ferroni,

Deputy Associate Administrator for Planning and Environment.

[FR Doc. 2023–18859 Filed 8–30–23; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Great Lakes St. Lawrence Seaway Development Corporation

Great Lakes St. Lawrence Seaway Development Corporation Advisory Board-Notice of Public Meetings; Correction

AGENCY: Great Lakes St. Lawrence Seaway Development Corporation, DOT.

ACTION: Notice; correction.

SUMMARY: The Great Lakes St. Lawrence Seaway Development Corporation (GLS) published a document in the **Federal Register** on December 19, 2022, providing notice of public meeting dates for the GLS Advisory Board. The date and location for the fourth meeting has changed.

FOR FURTHER INFORMATION CONTACT: Kevin O'Malley, Strategic Advisor for Financial and Resources Management, Great Lakes St. Lawrence Seaway Development Corporation, 1200 New Jersey Avenue SE, Suite W62–300, Washington, DC 20590; 202–366–0091.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 19, 2022, in FR Doc. 2022–27369, on page 77674, the following corrections are made:

1. In the second column, under the **DATES** caption, correct the fourth bullet and its sub bullets to read:

- Wednesday, November 29, 2023, from 2 p.m.–4 p.m. EST
  - Requests to attend the meeting must be received by November 24, 2023.
  - Requests for accommodations to a disability must be received by November 24, 2023.
  - If you wish to speak during the meeting, you must submit a written copy of your remarks to GLS by November 24, 2023.
  - Requests to submit written materials to be reviewed during the meeting must be received no later than November 24, 2023.

2. In the third column, under the **ADDRESS** caption, after the first sentence, add the following:

''The November 29, 2023, meeting will take place in-person in the Montreal A room at the Marriott Montreal Chateau Champlain hotel, 1050 Rue de la Gauchetiere West, Montreal, Quebec, Canada.''

3. In the third column, under the **SUPPLEMENTARY INFORMATION** caption, correct the fourth listed date to read:

''Wednesday, November 29, 2023, from 2 p.m.–4 p.m. EST''

Dated: August 28, 2023.

Carrie Lavigne,

Chief Counsel.

[FR Doc. 2023–18876 Filed 8–30–23; 8:45 am]

BILLING CODE 4910–61–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Revision of an Approved Information Collection; Submission for OMB Review; Conversions From Mutual to Stock Form

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning a revision to a currently approved information collection titled, ''Conversions from Mutual to Stock Form.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be received by October 2, 2023.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0347, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 293–4835.

Instructions: You must include ''OCC'' as the agency name and ''1557–0347'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Written comments and recommendations for the proposed information collection should also be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* You can find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' from the drop-down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching OMB control number ''1557–0347'' or ''Conversions from Mutual to Stock Form.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the

OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks OMB to approve this revised collection.

Title: Conversions from Mutual to Stock Form.

OMB Control No.: 1557–0347.

Abstract: Part 192 governs the process through which a savings association may convert from the mutual to the stock form of ownership and sets forth the procedures and submissions required in connection with that process.

Twelve CFR 192.5(c) provides that the appropriate Federal banking agency may waive any requirement of part 192 or any provision of a prescribed form. To obtain such a waiver, a savings association must file a written request with the agency that (1) specifies the requirement(s) or provision(s) for which the waiver is sought; (2) demonstrates that the waiver is equitable; is not detrimental to the savings association, its account holders, or other savings associations; and is not contrary to the public interest; and (3) includes a legal opinion demonstrating that the waiver sought does not conflict with applicable law.

Twelve CFR 192.105(a) sets forth the minimum requirements for the business plan a savings association must adopt prior to filing an application for conversion. The plan must include projections and activities for three years following the conversion; the plan for deploying conversion proceeds to meet credit and lending needs in proposed market areas; the risks associated with the plan for deployment of conversion proceeds and the effect of the plan on management resources, staffing, and facilities; the expertise of the savings association's management and board of directors; and plans for adequate staffing and controls to prudently manage the growth, expansion, new investment, and other operations and activities proposed in the business plan.

Twelve CFR 192.110(b) provides that upon review and approval of the savings association's business plan, the chief executive officer and at least two-thirds of the board must certify that the plan accurately reflects the intended plans for deployment of conversion proceeds and that any new initiatives reflected in the business plan are reasonably achievable. The savings association must submit these certifications with its business plan as part of its application for conversion under § 192.150.

Twelve CFR 192.130 provides that a savings association must include information included in §§ 192.320 (order of priority to purchase conversion shares) through 192.485 (liquidation account provision) and § 192.505 (restrictions on trading of shares) in its conversion plan.

Twelve CFR 192.135(a) provides that a savings association must notify its members that its board of directors has adopted a plan of conversion. This notification may be accomplished by mail or email, the posting of notices in local newspapers, or the posting of a notice on the savings association's website. Twelve CFR 192.135(b) sets forth the minimum requirements for the required notice, including information about the rights of account holders in connection with the conversion and the processes available to exercise those rights.

Twelve CFR 192.150 sets forth the information to be required in a savings association's application for conversion. The application must include: (1) the plan for conversion; (2) pricing materials meeting the requirements of § 192.200(b); (3) proxy materials under § 192.270; (4) an offering circular described in § 192.300; (5) documents and information required by Form AC; (6) any necessary written consents; (7) the savings association's business plan, submitted as a separately bound, confidential exhibit; and (8) any other information requested by the appropriate Federal banking agency.

Twelve CFR 192.180(a) requires a savings association to publish a public notice of its application for conversion by simultaneously posting the notice prominently in its home and branch offices. Twelve CFR 192.180(b) provides that a savings association must publish and post a new notice and allow an additional 30 days for comment if the savings association must refile an application.

Twelve CFR 192.225(a) requires that after the appropriate Federal banking agency approves the plan of conversion, the savings association must submit the plan to its members for approval and obtain approval at a special or annual meeting of its members. Twelve CFR 192.225(d) provides that a savings association may notify eligible account holders or supplemental eligible account holders who are not voting members of its proposed conversion and include only the information in § 192.135 in its notice.

Twelve CFR 192.235(a) provides that a savings association must notify its members of the meeting to consider its conversion by sending the members a proxy statement cleared by the appropriate Federal banking agency. Twelve CFR 192.235(c) requires the savings association to also notify each beneficial holder of an account held in a fiduciary capacity if the savings association is a Federal savings association and the name of the beneficial holder is disclosed on the savings association's records or if the savings association is a State-chartered savings association and the beneficial holder possesses voting rights under State law.

Twelve CFR 192.240(a) requires that, after the members meeting, the savings association file with the appropriate OCC licensing office (Federally-chartered) or FDIC region (State-chartered) the following information: (1) a certified copy of each adopted resolution on the conversion; (2) the total votes eligible to be cast; (3) the total votes represented in person or by proxy; (4) the total votes cast in favor of and against each matter; (5) the percentage of votes necessary to approve each matter; and (6) an opinion of counsel that the meeting was conducted in compliance with all applicable State or Federal laws and regulations. Twelve CFR 192.240(b) requires that, upon completion of the conversion, the savings association promptly submit an opinion of counsel that it complied with all applicable laws.

Twelve CFR 192.250(b)(2) requires that if, in complying with proxy solicitation provisions, the savings association solicits proxies through newspaper advertisements, the advertisements may include only (i) the name of the savings association; (ii) the reason for the advertisement; (iii) the proposal or proposals to be voted upon; (iv) where a member may obtain a copy of the proxy solicitation material; and (v) a request for the savings association's members to vote at the meeting.

Twelve CFR 192.255 sets forth the form of proxy requirements. The form of proxy must include the following: (a) a statement in bold face type stating that management is soliciting the proxy; (b) blank spaces where the member must date and sign the proxy; (c) clear and impartial identification of each matter or group of related matters that members will vote upon; (d) the phrase ''Revocable Proxy'' in bold face type (at least 18 point); (e) a description of any charter or State law requirement that restricts or conditions votes by proxy; (f) an acknowledgment that the member received a proxy statement before he or she signed the form of proxy; (g) the date, time, and the place of the meeting, when available; (h) a way for the

member to specify by ballot whether he or she approves or disapproves of each matter that members will vote upon; (i) a statement that management will vote the proxy in accordance with the member's specifications; and (j) a statement in bold face type indicating how management will vote the proxy if the member does not specify a choice for a matter.

Twelve CFR 192.270 requires that a savings association prepare its proxy statement in compliance with part 192 and Form PS and to mail proxy solicitation material to its members.

Twelve CFR 192.275(a) provides that a savings association must file revised proxy solicitation materials as an amendment to its application for conversion. The proxy solicitation materials must be in the form in which it furnished the materials to its members. Twelve CFR 192.275(b) provides that to revise its proxy a savings association must file (1) revised proxy materials as required by Form PS; (2) a revised form of proxy, if applicable; (3) any additional proxy solicitation material subject to § 192.270; and (4) a copy of the revised proxy solicitation materials marked to clearly indicate changes from the prior filing.

Twelve CFR 192.280 sets out the rules for mailing proxy solicitation materials. Twelve CFR 192.280(a) provides that a savings association must mail the member's cleared proxy solicitation material if a member requests in writing that the savings association mail the proxy solicitation material, if the savings association's board of directors has adopted a plan of conversion, the appropriate Federal banking agency has cleared the member's proxy solicitation, and the member agrees to defray the savings association's reasonable expenses. Twelve CFR 192.280(b) provides that upon receipt of such a request, the savings association must promptly furnish to the member the approximate number of members that the savings association solicited or will solicit (or the approximate number of members of any group of account holders that the member designates) and the estimated cost of mailing the proxy solicitation material.

Twelve CFR 192.295 provides that if a savings association amends its application for conversion, the appropriate Federal banking agency may require the savings association to re-solicit proxies for its members' meeting as a condition of approval of the amendment.

Twelve CFR 192.300 sets forth the requirements governing offering circulars. Twelve CFR 192.300(a) provides that a Federal savings association must file its offering circular with the appropriate OCC licensing office and a State savings association must file its offering circular with the appropriate FDIC region. Twelve CFR 192.300(b) provides that a savings association must condition its stock offering upon member approval of its plan of conversion.

Twelve CFR 192.305 sets forth rules governing the distribution of the offering circular. Twelve CFR 192.305(a) provides that a savings association may distribute a preliminary offering circular at the same time as or after it mails the proxy statement to its members. Twelve CFR 192.305(c) provides that a savings association must distribute a final offering circular for stock issued in the transaction to persons listed in its plan of conversion within ten calendar days after the appropriate Federal banking agency declares the offering circular effective or the Securities and Exchange Commission declares the registration statement for the offering circular effective.

Twelve CFR 192.310 sets forth the rules governing post-effective amendments to an offering circular. Twelve CFR 192.310(b) provides that after the appropriate Federal banking agency or the Securities and Exchange Commission declares the post-effective amendment effective, the savings association must immediately have the amendment to the offering circular delivered to each person who subscribed for or ordered shares in the offering. Twelve CFR 192.310(c) provides that the post-effective amendment must indicate that each person may increase, decrease, or rescind their subscription or order.

Twelve CFR 192.320 provides that a savings association must offer to sell its shares in the following order: (a) eligible account holders; (b) tax-qualified employee stock ownership plans; (c) supplemental eligible account holders; (d) other voting members who have subscription rights; and (e) the savings association's community or the general public.

Twelve CFR 192.335 sets forth the procedures for the sale of conversion shares. Twelve CFR 192.335(a) provides that savings association must distribute order forms to all eligible account holders, supplemental eligible account holders, and other voting members to enable them to subscribe for the conversion shares they are permitted under the plan of conversion. The savings association may either send the order forms with its offering circular or after the savings association distributes its offering circular.

Twelve CFR 192.405 sets forth the rules governing extensions of the offering period. Twelve CFR 192.405(b) provides that if the appropriate Federal banking agency grants a savings association's request for an extension of the offering period, the savings association must provide a post-effective amendment to the offering circular under § 192.310 to each person who subscribed for or ordered stock. The amendment must indicate that the appropriate Federal banking agency extended the offering period and that each person who subscribed for or ordered stock may increase, decrease, or rescind their subscription or order within the time remaining in the extension period.

Twelve CFR 192.430 sets forth the rules governing charter amendments. Twelve CFR 192.430(a) provides that if the savings association is a Federally-chartered mutual savings association or savings bank and it converts to a Federally-chartered stock savings association or savings bank, it must apply to the OCC to amend its charter and bylaws consistent with 12 CFR 5.22 as part of the savings association's application for conversion.

Twelve CFR 192.450(a) provides that a liquidation account represents the potential interest of eligible account holders and supplemental eligible account holders in the savings association's net worth at the time of conversion. A savings association must maintain a sub-account to reflect the interest of each account holder.

Twelve CFR 192.470 sets forth the rules governing adjustments to liquidation sub-accounts. Twelve CFR 192.470(a) provides that a savings association must reduce the balance of an eligible account holder's or supplemental eligible account holder's liquidation sub-account if the deposit balance in the account holder's savings account at the close of business on any annual closing date, falls below the lesser of: (i) the deposit balance in the account holder's savings account as of the relevant eligibility record date; or (ii) the deposit balance in the account holder's savings account as of its lowest balance as of any subsequent annual closing date. The reduction in the liquidation sub-account from its balance at the time of conversion must be proportionate to the reduction in the account holder's savings account from its balance at the time of conversion. Twelve CFR 192.470(c) provides that a savings association is not required to adjust the liquidation account and sub-account balances at each annual closing date if the savings association maintains sufficient records to make the

computations if a liquidation subsequently occurs. Twelve CFR 192.470(d) provides that a savings association must maintain the liquidation sub-account for each account holder as long as the account holder maintains an account with the same social security number.

Twelve CFR 192.485 provides that if a savings association converts to Federal stock form, it must include a specific provision regarding the maintenance of a liquidation account in its new charter.

Twelve CFR 192.500(a) provides that during the twelve months after its conversion, a savings association may implement a stock option plan (Option Plan), an employee stock ownership plan or other tax-qualified employee stock benefit plan (collectively, ESOP), and a management recognition plan (MRP), provided that the savings association meets a set of requirements, including disclosure requirements and percentage limitations, and vesting restrictions.

Twelve CFR 192.505 sets forth the rules governing restrictions on trading. Twelve CFR 192.505(b) provides that the savings association must include a notice of an applicable restriction on each certificate of stock that a director or officer purchases during the conversion or receives in connection with a stock dividend, stock split, or otherwise with respect to such restricted shares.

Twelve CFR 192.515 details the information that must be filed with the Federal banking agency prior to the repurchase of shares. Twelve CFR 192.515(a) provides that in order to repurchase stock in the first year following conversion, a savings association generally must file a written notice with the appropriate OCC licensing office if Federally-chartered and with the appropriate FDIC region if State-chartered. The savings association must provide the following information: (1) the proposed repurchase program; (2) the effect of the repurchases on regulatory capital; and (3) the purpose of the repurchases and, if applicable, an explanation of the extraordinary circumstances necessitating the repurchases. Twelve CFR 192.515(b) provides that a Federal savings association must file its notice with the appropriate OCC licensing office, and a State savings association must file its notice with the appropriate regional director of the FDIC, at least 10 calendar days before the savings association begins its repurchase program. Twelve CFR 192.515(c) provides that a savings association may not repurchase its shares if the appropriate Federal banking agency objects to the repurchase program.

Twelve CFR 192.525 sets forth the restrictions on the acquisition of shares after conversion. Twelve CFR 192.525(c)(5) provides that an acquiror does not have to file a separate application to obtain the appropriate Federal banking agency's approval under 12 CFR 192.525(a) if the acquiror files an application under 12 CFR 5.50 that specifically addresses the criteria listed under 12 CFR 192.525(d) and the savings association does not oppose the proposed acquisition. Twelve CFR 192.525(d) provides conditions under which the appropriate Federal banking agency may deny an application to acquire shares.

Twelve CFR 192.530 sets forth other post conversion requirements. Twelve CFR 192.530(a) provides that after a savings association converts, it must promptly register its shares under the Securities Exchange Act of 1934 (15 U.S.C. 78a–78jj, as amended). The savings association may not deregister the shares for three years. Twelve CFR 192.530(c) provides that a savings association must also use its best efforts to list its shares on a national or regional securities exchange or on the National Association of Securities Dealers Automated Quotation system. Finally, 12 CFR 192.530(d) requires the savings association to file all post-conversion reports required by the appropriate Federal banking agency.

Twelve CFR 192.550(a) provides that a savings association may contribute some of its conversion shares or proceeds to a charitable organization if its plan of conversion provides for the proposed contribution.

Twelve CFR 192.565 provides that the charter of a charitable organization's charter (or trust agreement) and the gift instrument itself must provide that: (a) the charitable organization's primary purpose is to serve and make grants in the savings association's local community; (b) as long as the charitable organization controls shares, it must vote those shares in the same ratio as all other shares voted on each proposal considered by the savings association's shareholders; (c) for at least five years after its organization, one seat on the charitable organization's board of directors (or board of trustees) is reserved for an independent director (or trustee) from the savings association's local community who is not affiliated with the savings association and experienced with local community charitable organizations and grant making; and (d) for at least five years after its organization, one seat on the charitable organization's board of directors (or board of trustees) is reserved for a director from the savings association's board of directors.

Twelve CFR 192.575(a) provides that the charitable organization's charter (or trust agreement) and the gift instrument for the contribution must provide that: (1) the appropriate Federal banking agency may examine the charitable organization at the charitable organization's expense; (2) the organization must comply with all supervisory directives that the appropriate Federal banking agency imposes; (3) the organization must operate according to written policies adopted by its board of directors (or board of trustees), including a conflict of interest policy; (4) the organization must not engage in self-dealing; and (5) the organization must comply with all laws necessary to maintain its tax-exempt status under the Internal Revenue Code. Twelve CFR 192.575(b) provides that the savings association must include a specific legend in the stock certificates of shares that the savings association contributes to the charitable organization or that the charitable organization otherwise acquires.

Twelve CFR 192.650 provides that a majority of the board of directors of the savings association must adopt a plan of voluntary supervisory conversion. The savings association must include in its plan of voluntary supervisory conversion: (a) the savings association's name and address; (b) a description of the proposed voluntary supervisory conversion transaction that also describes plans for any liquidation account; and (c) certified copies of all resolutions relating to the conversion adopted by the board of directors of the savings association.

Twelve CFR 192.660 provides that a savings association must include all of the following information and documents in a voluntary supervisory conversion application to the appropriate OCC licensing office if it is a Federal savings association and to the appropriate FDIC region if it is a State savings association under this subpart: (a) information establishing eligibility; (b) a plan of conversion that complies with § 192.650; (c) a business plan that complies with § 192.105, when required by the appropriate Federal banking agency; (d) financial data, including financial statements and call reports, to support the transaction; (e) proposed documents for the conversion (charter, bylaws, stock certificate, securities disclosure materials); (f) any agreements between the savings association and proposed purchasers and all existing and proposed employment contracts; (g) all related filings and applications

including, filings required under the securities offering rules of 12 CFR parts 16 and 192, Change in Bank Control Act submissions, subordinated debt applications, applications for permission to organize a stock association and for approval of a merger, applications for FDIC insurance of accounts); and (h) other information, including a statement describing post-conversion roles for officers, directors, and affiliates and waiver requests.

Type of Review: Revision.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 1.

Estimated Total Annual Burden: 512 hours.

Comments: On June 07, 2023, the OCC published a 60-day notice for this information collection, (88 FR 37305). No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2023–18808 Filed 8–30–23; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Supervisory Guidance: Supervisory Review Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, ''Supervisory Guidance: Supervisory Review Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be received by October 2, 2023.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible.

You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0242, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 293–4835.

Instructions: You must include ''OCC'' as the agency name and ''1557–0242'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Written comments and recommendations for the proposed information collection should also be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* You can find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- Viewing Comments Electronically: Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' from the drop-down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching OMB control number ''1557–0242'' or ''Supervisory Guidance: Supervisory Review Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks the OMB to extend its approval of the collection in this notice.

Title: Supervisory Guidance: Supervisory Review Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework.

OMB Control No.: 1557–0242.

Frequency of Response: Event-generated.

Affected Public: National banks and Federal savings associations subject to the advanced approaches capital rule.

Abstract: In 2008, the OCC, Board of Governors of the Federal Reserve System, and Federal Deposit Insurance Corporation issued a supervisory guidance document to assist banking organizations in implementing the

supervisory review process, or Pillar 2, of the advanced approaches risk-based capital rule.[1] This guidance is relevant for OCC-supervised national banks and Federal savings associations (collectively, banks) that are subject to the advanced approaches capital rule.[2] It does not apply to small banks.

Paragraphs 37, 41, 43, and 46 of the guidance contain information collections. Paragraph 37 provides that banks should clearly state the definition of capital used in any aspect of its internal capital adequacy assessment process (ICAAP) and document any changes in the internal definition of capital. Paragraph 41 provides that banks should maintain thorough documentation of ICAAP, as detailed in the paragraph. Paragraph 43 specifies that the board of directors should approve the bank's ICAAP, review it on a regular basis, and approve any changes. Paragraph 46 provides that the board of directors and appropriate senior management should periodically, but at least annually, review the assessment of overall capital adequacy and analyze how measures of internal capital adequacy compare with other capital measures (such as regulatory, accounting-based, or market-determined).

Estimated Burden:

Number of Respondents: 20.

Estimated Burden per Respondent: 140 hours.

Total Estimated Annual Burden: 2,800.

Comments: On May 24, 2023, the OCC published a notice for 60 days of comment concerning this information collection, 88 FR 33665. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2023–18813 Filed 8–30–23; 8:45 am]

BILLING CODE 4810–33–P

[1] 73 FR 44620 (July 31, 2008).

[2] *See* 12 CFR 3.100(b).

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs (VA), Office of Small & Disadvantaged Business Utilization (OSDBU).

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, notice is hereby given that the VA is modifying the system of records entitled, ''Veterans Enterprise Management System (VEMS)–VA'' (181VAOSDBU). This system provides VA personnel with access to resources that allow them to perform market research on Veteran Owned Small Businesses (VOSB) and Service-Disabled Veteran Owned Small Businesses (SDVOSB). The system also provides a platform for registration and announcement of VA OSDBU supported events, as well as provides OSDBU with the data and reports needed to manage their responsibilities under the Veterans Entrepreneurship and Small Business Development Act of 1999.

DATES: Comments on this modified system of records must be received no later than 30 days after date of publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the modified system of records will become effective a minimum of 30 days after date of publication in the **Federal Register**. If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to VA Privacy Service, 810 Vermont Avenue NW, (005X6F), Washington, DC 20420. Comments should indicate that they are submitted in response to Veterans Enterprise Management System VA VetBiz Portal-VA (181VAOSDBU). Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: For general questions about the system contact Carol Cleveland at Office of Small & Disadvantaged Business Utilization at 810 I Street NW, Washington, DC 20420, *osdbuexeccorr@va.gov* and (202) 461–4600 (Note: this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The purpose of this modified system of records is to notify that VA will no longer gather information to substantiate that small businesses owned and controlled by Veterans are qualified for contracts under the Vets First Program. The Small Business Administration has taken over these functions as directed in the William H. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021. The social security number and date of birth fields will be stripped from the system contact records. Personal and professional papers gathered to support the Verification Program will be disposed of in accordance with applicable records control schedule.

The Report of Intent to Amend a System of Records Notice and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by the Privacy Act and guidelines issued by OMB, December 12, 2000.

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document 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. Kurt D. DelBene, Assistant Secretary for Information and Technology and Chief Information Officer, approved this document on July 27, 2023 for publication.

Dated: August 28, 2023.

Amy L. Rose,

Government Information Specialist, VA Privacy Service, Office of Compliance, Risk and Remediation, Office of Information and Technology, Department of Veterans Affairs.

SYSTEM NAME AND NUMBER:

Veterans Enterprise Management System (VEMS) VA VetBiz Portal–VA (181VAOSDBU).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The system is hosted on the VA Enterprise Cloud (EC), Microsoft Azure Government (MAG). The VA EC MAG is

in Azure Government Region 1, Region 2, or Region 3.

SYSTEM MANAGER:

Carol Cleveland, Information Technology Systems Integration Program Manager, VA Office of Small & Disadvantaged Business Utilization (OSDBU), 810 Vermont Avenue NW, Room 1064, Washington, DC 20420. *Carol.Cleveland@VA.GOV, osdbuexeccorr@va.gov* and (202) 461–4600.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

38 U.S.C. 8127 and Public Law 106–50.

PURPOSE(S) OF THE SYSTEM:

1. Provide VA personnel with access to resources that allow them to perform market research upon Veteran Owned Small Businesses (VOSB) and Service-Disabled Veteran Owned Small Businesses (SDVOSB).

2. Provide a platform for registration and announcement of all VA OSDBU supported events.

3. Provides the OSDBU with the data and reports needed to manage their responsibilities under the Veterans Entrepreneurship and Small Business Development Act of 1999.

4. Provide information to VA personnel to use in counseling and assisting small business owners and Veteran entrepreneurs in starting a small business or expanding an existing small business.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records will cover small business owners, Veteran entrepreneurs, large business partners, other small business support partners and VA program and acquisition officials.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records will contain data on VetBiz Portal users. The records may include name, personal mailing address, personal email address, tax identification number, contract acquisition data revenue, environment identifier, agency contract, figures, position title, VISN, office, provider ID., Fedmine module, user ID (Guid), company certification, company org, GSA contract, SAM UEI, is verified, primary email, company type, bonding level, CVE verification date, year established, employees number, employees number vet, is veteran, is minority owned, is service disabled, is WOSB, certified cor, contract acquisition data revenue, sec ID (Guid), title of an event, date of an event, location, company name.

RECORD SOURCE CATEGORIES:

The information in this system of records is obtained from the following sources:

a. Information voluntarily submitted by the user;

b. Information gathered from official VA data sources such as Identity Access Management; and

c. Public information extracted from other business databases, Small Business Administration VetCert database and *www.Fedmine.us,* a GovSpend Company.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. Congress

To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

2. Data Breach Response and Remediation, for VA

To appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that there has been a breach of the system of records; (2) VA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, VA (including its information systems, programs, and operations), and the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with VA's efforts to respond to the suspected or confirmed breach or to prevent, minimize or remedy such harm.

3. Law Enforcement

To a Federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing such law, provided that the disclosure is limited to information that, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature. The disclosure of the names and addresses of veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701. Data Breach Response and Remediation, for Another Federal Agency.

To another Federal agency or Federal entity, when VA determines that the information is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

4. DoJ for Litigation or Administrative Proceeding

To the Department of Justice (DoJ), or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when:

(a) VA or any component thereof;

(b) Any VA employee in his or her official capacity;

(c) Any VA employee in his or her individual capacity where DoJ has agreed to represent the employee; or

(d) The United States, where VA determines that litigation is likely to affect the agency or any of its components, is a party to such proceedings or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings.

5. Contractors

To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records.

6. OPM

To the Office of Personnel Management (OPM) in connection with the application or effect of civil service laws, rules, regulations, or OPM guidelines in particular situations.

7. Federal Agencies, for Research

To a Federal agency for the purpose of conducting research and data analysis to perform a statutory purpose of that Federal agency upon the prior written request of that agency.

8. Federal Agencies, for Computer Matches

To other federal agencies for the purpose of conducting computer matches to obtain information to determine or verify eligibility of Veterans receiving VA benefits or medical care under Title 38, U.S.C.

9. Federal Agencies, Courts, Litigants, for Litigation or Administrative Proceedings

To another federal agency, court, or party in litigation before a court or in an administrative proceeding conducted by a Federal agency, when the government is a party to the judicial or administrative proceeding.

10. Governmental Agencies, for VA Hiring, Security Clearance, Contract, License, Grant

To a Federal, state, local, or other governmental agency maintaining civil or criminal violation records, or other pertinent information, such as employment history, background investigations, or personal or educational background, to obtain information relevant to VA's hiring, transfer, or retention of an employee, issuance of a security clearance, letting of a contract, or issuance of a license, grant, or other benefit. The disclosure of the names and addresses of Veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

11. State or Local Agencies, for Employment

To a state, local, or other governmental agency, upon its official request, as relevant and necessary to that agency's decision on the hiring, transfer, or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit by that agency. The disclosure of the names and addresses of Veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system will be stored in a computerized database. The system will operate on servers, located on the VA EC MAG, Region 1 and Region 2, or Region 3. Data backups will reside on appropriate media, according to normal system backup plans for VA Enterprise Operations.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records in this system may be retrieved by:

1. Organization Name.
2. Contact Name.
3. Email Address.
4. Web Address.
5. Area Code and Phone Number.
6. Zip Code.
7. County Code (NaCO).
8. State(s).
9. Service Area Limits (if any).
10. Year Established.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained and disposed of in accordance with the schedule approved by the Archivist of the United States, DAA–0015–2018–0003, 7 years from the date the records were last modified or updated.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

VA staff and contractors will have access to the system via VA Intranet and local connections, for operations, management and maintenance purposes and tasks. Access to the Intranet portion of the system is done through VA PIV authentication and role-based access control at officially approved access points. Small business owners and Veteran entrepreneurs will establish and maintain user ID's and passwords for accessing the VetBiz Portal using VA's DS Logon, *ID.me* or *Login.gov* through Access VA. Policy regarding issuance of user-ids and passwords is formulated in VA by the Office of Information and Technology, Washington, DC. The system is configured so that access to the public data elements in the database does not lead to access to the non-public data elements.

RECORD ACCESS PROCEDURES:

Individuals seeking information on the existence and content of records in this system pertaining to them should contact the system manager in writing as indicated above. A request for access to records must contain the requester's full name, address, telephone number, be signed by the requester, and describe the records sought in sufficient detail to enable VA personnel to locate them with a reasonable amount of effort.

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records in this system pertaining to them should contact the system manager in writing as indicated above. A request to contest or amend records must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record.

NOTIFICATION PROCEDURES:

Generalized notice is provided by the publication of this notice. For specific notice, see Record Access Procedure, above. E

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

87 FR 1007 (January 7, 2022).

[FR Doc. 2023–18874 Filed 8–30–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Minority Veterans, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5. U.S.C. ch.10, that the Advisory Committee on Minority Veterans will virtually meet on September 28, 2023 via Microsoft Teams. The meeting sessions will begin, and end as follows:

Dates	Times
September 28, 2023.	11:00 a.m.–2:30 p.m.—Eastern Standard Time (EST).

This meeting is open to the public.

The purposes of the Committee is to advise the Secretary of Veterans Affairs with respect to the administration of benefits by VA for Veterans who are minority group members, by reviewing reports and studies on compensation, health care, rehabilitation, outreach and other benefits and services administered by the Department.

On September 28, the Committee will receive briefings and updates from the VA Deputy Chief of Staff, Center for Minority Veterans, and Board of Veterans Appeals. The Committee will receive public comments from 1:45 p.m. to 2:00 p.m. EST. The Committee will conduct an after-action review.

Individuals who wish to provide public comment are invited to submit a 1–2-page summary of their comments no later than September 21, 2023 for inclusion in the official meeting record. Members of the public may also submit written statements for the Committee's review to Mr. Dwayne Campbell, at *Dwayne.Campbell3@va.gov.*

To access the Microsoft Teams meeting, dial the number shown here: 1 872–701–0185, 886289631# Phone Conference ID: 886 289 631#.

Any member of the public seeking additional information should contact Mr. Dwayne Campbell or Mr. Ronald Sagudan at (202) 461–6191.

Dated: August 28, 2023.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2023–18884 Filed 8–30–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs (VA), Office of Information of Technology, Financial Service Center (FSC).

ACTION: Notice of modified system of records.

SUMMARY: Individuals Submitting Invoices-Vouchers for Payment and Accounting Transactional Data-VA (13VA047) is a compilation of records

received, controlled, managed, and employed for payment processing; general accounting; benefit payment distribution to veterans and their families; commercial vendor invoices for contract and reimbursement expenditures; payroll payments; and commercial government procurement and contracting data.

DATES: Comments on this modified system of records must be received no later than 30 days after date of publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the modified system of records will become effective a minimum of 30 days after date of publication in the **Federal Register**. If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary.

ADDRESSES: Written comments may be submitted through *www.Regulation.gov;* by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Ave. NW, Room 1064, Washington, DC 20420; or by fax to (202) 273–9026 (not a toll-free number). Comments should indicate that they are submitted in response to ''Individuals Submitting Invoices-Vouchers for Payment and Accounting Transactional Data-VA'' (13VA047). Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, comments may be viewed online at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jonathan Lindow, Director, Operations and Management Division, Financial Services Center, 7600 Metropolis Dr., Austin, TX 78744, *Jonathan.Lindow@va.gov,* 512–568–0626.

SUPPLEMENTARY INFORMATION: The Point-of-Contact (POC), system manager and routine uses are being modified in this ''Individuals Submitting Invoices Vouchers for Payment and Accounting Transactional Data-VA'' (13VA047), along with some changes to covered systems. Individuals Submitting Invoices-Vouchers for Payment and Accounting Transactional Data-VA is a VA-wide financial management system of records utilized in VA's IT accounting systems for payment of benefits, vendor payments, invoice payment processing, payroll purposes, and acquisition records pertinent to maintaining acquisition methods, costs and processes. Information is collected from recipients, vendors, VA administrations, medical centers, and other Federal entities for rendering payment. This includes information on businesses and persons as a business conducting business with VA. Business/person's names may be duplicative requiring another method to ensure the correct business/person is identified. Data Universal Numbers (DUNs), Unique Entity Identifier (UEI) and/or Tax Identification Numbers (TINs) or Employment Identification Numbers (EIN) are used by businesses. In some cases, persons will use their social security number (SSN) as the TIN.

Updated authorities by which the data is collected are 31 U.S. Code 3512—Executive Agency Accounting and other Financial Management Reports and Plans; Federal Managers' Financial Integrity Act section 2 of 1982; Federal Financial Management Improvement Act of 1996; E-Government Act of 2002 title III., Federal Information Security Management Act (FISMA); Clinger Cohen Act of 1996; 38 CFR part 17 17.120–17.132; OMB Circular A–123, *Management's Responsibility for Internal Control.*

Additional Routine Uses were added based on revised guidelines to A–108 and updated standards for agency breach notification. Moreover, VA must be able to provide its own initiative information that pertains to a violation of laws to law enforcement authorities in order for them to investigate and enforce those laws. Under 38 U.S.C. 5701(a) and (f), VA may only disclose the names and addresses of veterans and their dependents to Federal entities with law enforcement responsibilities. This is distinct from the authority to disclose records in response to a qualifying request from a law enforcement entity, as authorized by Privacy Act subsection 5 U.S.C. 552a(b)(7). VA will administer financial and transactional information through benefit disbursement consuming HIPPA related data thus amending the routine uses to include: 14. Federal Agencies, Hospitals, for Referral by VA.; 15. Non-VA Doc, for Referral to VA; 25. Claims Representatives; and 26. Third Party, for Benefit or Discharge. Location of the system of records is a notable change to being stored, managed, and secured within a momentum cloud application.

Numerical order of routine uses from original SORN listing to revised version is amended to the below agency standardized format including the first ten routine uses:

1. Congress.
2. Data breach response and remedial efforts.
3. Data breach response and remedial efforts with another Federal agency.
4. Law Enforcement.
5. Litigation.
6. Contractors.
7. EEOC.
8. FLRA.
9. MSPB.
10. NARA & GSA.

Data breach response and remedial efforts. VA may, on its own initiative, disclose information from this system to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that there has been a breach of the system of records; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to individuals, the Department (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosures by the Department to respond to a suspected or confirmed data breach, including the conduct of any risk analysis or provision of credit protection services as provided in 38 U.S.C. 5724 and, in accordance with Veterans Benefits, Health Care, and Information Technology Act of 2006 5723–5724.

Data breach response and remedial efforts, for another Federal agency. VA may, on its own initiative, disclose information from this system to another Federal agency or Federal entity, when VA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach. In accordance with 38 U.S.C. 5723, VA will ensure that the Assistant Secretary for Information and Technology, in coordination with the Under Secretaries, Assistant Secretaries, and other key officials of the Department report to Congress, the Office of Management and Budget, and other entities as required by law and this section of the regulation to cooperate with notify and cooperate with officials other than officials of the Department of

data breaches when required. Use of information is necessary and proper to initiate investigations into confirmed data breaches involving other executive branch agencies.

Law Enforcement. VA may, on its own initiative, disclose information in this system, except the names and home addresses of veterans and their dependents, which is relevant to a suspected or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, to a Federal, State, local, Tribal, or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule or order. VA may also disclose the names and addresses of veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto. Use of information is necessary and proper to cooperate with other federal agencies while prosecuting civil, criminal or regulatory violations of law.

Litigation. VA may disclose information to the Department of Justice (DoJ) or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when:

(a) VA or any component thereof;

(b) Any VA employee in his or her official capacity;

(c) Any VA employee in his or her individual capacity where DoJ has agreed to represent the employee; or

(d) The United States, where VA determines that litigation is likely to affect the agency or any of its components is a party to such proceedings or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings.

Contractors. VA may disclose information from this system of records to contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records., in order for the contractor, subcontractor, public or private agency, or other entity or individual with whom VA has a contract or agreement to perform services under the contract or agreement. This routine use includes disclosures by an individual or entity performing services for VA to any secondary entity or individual to perform an activity that is necessary for individuals, organizations, private or public agencies, or other entities or individuals with whom VA has a contract or agreement to provide the service to VA. This routine use also applies to agreements that do not qualify as contracts defined by Federal procurement laws and regulations. VA may disclose information from this system of records to individuals, organizations private or public agencies, or other entities or individuals with whom VA has a contract or agreement to perform such services by contract or agreement, and performing duties on behalf of VA.

EEOC. VA may disclose information from this system to the Equal Employment Opportunity Commission (EEOC) when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law or regulation. VA must be able to provide information to EEOC to assist it in fulfilling its duties to protect employees' rights, as required by statute and regulation, and to protect VA employee rights.

FLRA. VA may disclose information from this system to the Federal Labor Relations Authority (FLRA), including its General Counsel, information related to the establishment of jurisdiction, investigation, and resolution of allegations of unfair labor practices, or in connection with the resolution of exceptions to arbitration awards when a question of material fact is raised; for it to address matters properly before the Federal Services Impasses Panel, investigate representation petitions, and conduct or supervise representation elections. VA must be able to provide information to FLRA to comply with the statutory mandate under which it operates and to cooperate with labor relation investigations.

MSPB. VA may disclose information from this system to the Merit Systems Protection Board (MSPB) when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law. VA must be able to provide information to MSPB to assist it in fulfilling its duties as required by statute and regulation and to cooperate with Merit Systems Protection Board concerning allegations of prohibited personnel practices. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Federal Agencies, for Computer Matches. VA may disclose identifying information, including social security number, concerning veterans, spouses of veterans, and the beneficiaries of veterans to other federal agencies for the purpose of conducting computer matches to obtain information to determine or verify eligibility of veterans receiving VA medical care under Title 38, U.S.C. VA must be able to provide limited personally identifiable information to other federal agencies for computer matching activities for the purpose of benefit payments to veterans and beneficiaries.

Federal Agencies, Hospitals, for Referral by VA. VA may disclose relevant health care information to: (1) a federal agency or non-VA health care provider or institution when VA refers a patient for hospital or nursing home care or medical services, or authorizes a patient to obtain non-VA medical services and the information is needed by the federal agency or non-VA institution on provider to perform the services; or (2) a federal agency or to a non-VA hospital (federal, state, and local public or private) or other medical installation having hospital facilities, organ banks, blood banks, or similar institutions, medical schools or clinics, or other groups or individuals that have contracted or agreed to provide medical services or share the use of medical resources under the provisions of 38 U.S.C. 513, 7409, 8111, or 8153, when treatment is rendered by VA under the terms of such contract or agreement or the issuance of an authorization, and the information is needed for purposes of medical treatment and/or follow-up, determining entitlement to a benefit, or for VA to effect recovery of the costs of the medical care. VA must be able to provide patient referral information for authorized hospital and/or nursing home care to a non-VA medical services provider for recovery of the costs of the medical care.

Federal Agencies, for Recovery of Medical Care Costs. VA may disclose patient identifying information to federal agencies and VA and government-wide third-party insurers responsible for payment of the cost of medical care for the identified patients, in order for VA to seek recovery of the medical care costs. These records may also be disclosed as part of a computer matching program to accomplish this purpose. Use of information is necessary

and proper as data within this system does not exclusively include financial, transactional, and benefit payout data.

Treasury, IRS. VA may disclose the name of a veteran or beneficiary, other information as is reasonably necessary to identify such individual, and any other information concerning the individual's indebtedness by virtue of a person's participation in a benefits program administered by VA, may be disclosed to the Department of the Treasury, Internal Revenue Service, for the collection of Title 38 benefit overpayments, overdue indebtedness, and/or costs of services provided to an individual not entitled to such services, by the withholding of all or a portion of the person's Federal income tax refund. The purpose of this disclosure is to collect a debt owed the VA by an individual by offset of his or her Federal income tax refund.

Treasury, to Report Waived Debt as Income. VA may disclose an individual's name, address, social security number, and the amount (excluding interest) of any indebtedness which is waived under 38 U.S.C. 3102, compromised under 4 CFR part 103, otherwise forgiven, or for which the applicable statute of limitations for enforcing collection has expired, to the Department of the Treasury, Internal Revenue Service, as a report of income under 26 U.S.C. 61(a)(12).

Treasury, for Payment or Reimbursement. VA may disclose information to the Department of the Treasury to facilitate payments to physicians, clinics, and pharmacies for reimbursement of services rendered, and to veterans for reimbursements of authorized expenses, or to collect, by set off or otherwise, debts owed the United States. Justification—VA established standardized Guardians Ad Litem, for Representation.VA may disclose information to a fiduciary or guardian ad litem in relation to his or her representation of a claimant in any legal proceeding, but only to the extent necessary to fulfill the duties of the fiduciary or guardian ad litem. This disclosure permits VA to provide individual information to an appointed VA Federal fiduciary or to the individual's guardian ad litem that is needed to fulfill appointed duties.

Guardians, for Incompetent Veterans. VA may disclose relevant information from this system of records in the course of presenting evidence to a court, magistrate, or administrative tribunal; in matters of guardianship, inquests, and commitments; to private attorneys representing veterans rated incompetent in conjunction with issuance of Certificates of Incompetency; and to probation and parole officers in connection with court-required duties.

Claims Representatives. VA may disclose information from this system of records relevant to a claim of a veteran or beneficiary, such as the name, address, the basis and nature of a claim, amount of benefit payment information, medical information, and military service and active duty separation information, at the request of the claimant to accredited service organizations, VA-approved claim agents, and attorneys acting under a declaration of representation, so that these individuals can aid claimants in the preparation, presentation, and prosecution of claims under the laws administered by VA. The name and address of a claimant will not, however, be disclosed to these individuals under this routine use if the claimant has not requested the assistance of an accredited service organization, claims agent or an attorney. VA must be able to disclose this information to accredited service organizations, VA-approved claim agents, and attorneys representing veterans so they can assist veterans by preparing, presenting, and prosecuting claims under the laws administered by VA.

Third Party, for Benefit or Discharge. Health care information concerning a non-judicially declared incompetent patient may be disclosed to a third party upon the written authorization of the patient's next of kin in order for the patient, or, consistent with the best interest of the patient, a member of the patient's family, to receive a benefit to which the patient or family member is entitled, or, to arrange for the patient's discharge from a VA medical facility. Sufficient data to make an informed determination will be made available to such next of kin. If the patient's next of kin are not reasonably accessible, the Chief of Staff, Director, or designee of the custodial VA medical facility may disclose health information for these purposes.

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document 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. Kurt D. DelBene, Assistant Secretary for Information and Technology and Chief Information Officer, approved this document on July 25, 2023 for publication.

Dated: August 28, 2023.

Amy L. Rose,

Government Information Specialist, VA Privacy Service, Office of Compliance, Risk and Remediation, Office of Information and Technology, Department of Veterans Affairs.

SYSTEM NAME:

''Individuals Submitting Invoices-Vouchers for Payment and Accounting Transactional Data-VA'' (13VA047).

SECURITY CLASSIFICATION:

The information in this system is unclassified.

SYSTEM LOCATION:

VA Data Processing Center, Austin, Texas and fiscal offices of Central Office; field stations where fiscal transactions are processed; and application servers located in the VA managed enterprise service cloud enclave.

SYSTEM MANAGER(S):

Jonathan Lindow, Information System Owner, VA Financial Services Center (FSC), 7600 Metropolis Dr., Austin, TX 78744, *Jonathan.Lindow@va.gov,* (512) 981–4871. Pamela Smith, VA FSC Privacy Officer, Financial Services Center, 7600 Metropolis Dr., Austin, TX 78744, *Pamela.Smith6@va.gov,* (512) 937–4824.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S. Code 3512- Executive Agency Accounting and other Financial Management Reports and Plans; Federal Managers' Financial Integrity Act section 2 of 1982; Federal Financial Management Improvement Act of 1996; E-Government Act of 2002 title III., Federal Information Security Modernization Act (FISMA) of 2014; Clinger Cohen Act of 1996; 38 CFR part 17 17.120–17.132; OMB Circular A–123, *Management's Responsibility for Internal Control.*

PURPOSE(S) OF THE SYSTEM:

Individuals Submitting Invoices-Vouchers for Payment and Accounting Transactional Data-VA is a VA-wide financial management system of records utilized in VA's IT accounting systems for payment of benefits, vendor payments, invoice payment processing, and payroll purposes. Information is collected from recipients, vendors, VA administrations, medical centers, and other Federal entities for rendering payment.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

VA Employees, VA Contractors, VA Volunteers, Veterans or Dependents, and Members of the Public and Individuals.

CATEGORIES OF RECORDS IN THE SYSTEM:

Commercial Vendor identification listings, invoiced payment records, claimant information, and banking and financial accounting information, including Full name, Address, Phone Number, Social Security Number, Medical Records, Claim/Statement Number, Date of Service, Beneficiary Information, Email Address, Date of Birth, Driver License (Number and State), License Plate, Place of Birth (City, State and Country), Banking Information (Routing/Bank Account Number, and Bank Name), Charge Card Number, Emergency Contact Information, and Unique Entity Identifier (UEI).

RECORD SOURCE CATEGORIES:

Commercial vendors; individual or legal representative as part of an application for a benefit, contract or reimbursement; Data could potentially be obtained from a VA administration, facility and/or medical center; Department of the Treasury; Internal Revenue Service; and other Federal entities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. *Congress:* To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

2. *Data breach response and remediation, for VA:* To appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that there has been a breach of the system of records,· (2) VA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, VA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with VA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

3. *Data breach response and remediation, for another Federal agency:* To another Federal agency or Federal entity, when VA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

4. *Law Enforcement:* To a Federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing such law, provided that the disclosure is limited to information that, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature. The disclosure of the names and addresses of veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

5. *DoJ for Litigation or Administrative Proceeding:* To the Department of Justice (DoJ), or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when:

(a) VA or any component thereof;

(b) Any VA employee in his or her official capacity;

(c) Any VA employee in his or her individual capacity where DoJ has agreed to represent the employee; or

(d) The United States, where VA determines that litigation is likely to affect the agency or any of its components, is a party to such proceedings or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings.

6. *Contractors:* To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records.

7. *OPM:* To the Office of Personnel Management (OPM) in connection with the application or effect of civil service laws, rules, regulations, or OPM guidelines in particular situations.

8. *EEOC:* To the Equal Employment Opportunity Commission (EEOC) in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law.

9. *FLRA:* To the Federal Labor Relations Authority (FLRA) in connection with the investigation and resolution of allegations of unfair labor practices, the resolution of exceptions to arbitration awards when a question of material fact is raised, matters before the Federal Service Impasses Panel, and the investigation of representation petitions and the conduct or supervision of representation elections.

10. *MSPB:* To the Merit Systems Protection Board (MSPB) in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

11. *NARA:* To the National Archives and Records Administration (NARA) in records management inspections conducted under 44 U.S.C. 2904 and 2906, or other functions authorized by laws and policies governing NARA operations and VA records management responsibilities.

12. *Federal Agencies, for Computer Matches:* To other federal agencies for the purpose of conducting computer matches to obtain information to determine or verify eligibility of veterans receiving VA benefits or medical care under title 38.

13. *Federal Agencies, Courts, Litigants, for Litigation or Administrative Proceedings:* To another federal agency, court, or party in litigation before a court or in an administrative proceeding conducted by a Federal agency, when the government is a party to the judicial or administrative proceeding.

14. *Health Care Providers, for Referral by VA:* To: (1) a federal agency or health care provider when VA refers a patient for medical and other health services, or authorizes a patient to obtain such services and the information is needed by the federal agency or health care provider to perform the services; or (2) a federal agency or to health care provider under the provisions of 38 U.S.C. 513, 7409, 8111, or 8153, when treatment is rendered by VA under the terms of such contract or agreement or the issuance of an authorization, and the information is needed for purposes of medical treatment or follow-up, determination of eligibility for benefits, or recovery by VA of the costs of the treatment.

15. *Health Care Providers, for Referral to VA:* To a non-VA health care provider when that health care provider has referred the individual to VA for medical or other health services.

16. *Federal Agencies, for Recovery of Medical Care Costs:* To Federal agencies and government-wide third-party insurers responsible for payment of the cost of medical care for the identified patients, to seek recovery of the medical care costs. These records may also be

disclosed as part of a computer matching program to accomplish this purpose.

17. *Treasury, for Withholding:* To the Department of the Treasury for the collection of title 38 benefit overpayments, overdue indebtedness, or costs of services provided to an individual not entitled to such services, by the withholding of all or a portion of the person's Federal income tax refund, provided that the disclosure is limited to information concerning an individual's indebtedness by virtue of a person's participation in a benefits program administered by VA.

18. *Treasury, to Report Waived Debt as Income:* To the Department of the Treasury as a report of income under 26 U.S.C. 61(a)(12), provided that the disclosure is limited to information concerning an individual's indebtedness that is waived under 38 U.S.C. 3102, compromised under 4 CFR part 103, otherwise forgiven, or for which the applicable statute of limitations for enforcing collection has expired.

19. *Treasury, for Payment or Reimbursement:* To the Department of the Treasury to facilitate payments to physicians, clinics, and pharmacies for reimbursement of services rendered or to veterans for reimbursement of authorized expenses, as well as to collect, by set off or otherwise, debts owed the United States.

20. *Guardians Ad Litem, for Representation:* To a fiduciary or guardian ad litem in relation to his or her representation of a claimant in any legal proceeding as relevant and necessary to fulfill the duties of the fiduciary or guardian ad litem.

21. *Guardians, Courts, for Incompetent Veterans:* To a court, magistrate, or administrative tribunal in matters of guardianship, inquests, and commitments; to private attorneys representing veterans rated incompetent in conjunction with issuance of Certificates of Incompetency; or to probation and parole officers in connection with court-required duties.

22. *Claims Representatives:* To accredited service organizations, VA-approved claim agents, and attorneys acting under a declaration of representation, so that these individuals can aid claimants in the preparation, presentation, and prosecution of claims under the laws administered by VA upon the request of the claimant and provided that the disclosure is limited to information relevant to a claim, such as the name, address, the basis and nature of a claim, amount of benefit payment information, medical information, and military service and active duty separation information.

23. *Third Party, for Benefit or Discharge:* To a third party upon the written request of the patient's next-of-kin in order for a non-judicially declared incompetent patient or, consistent with the best interest of the patient, a member of the patient's family to receive a benefit to which the patient or family member is entitled or to arrange for the patient's discharge from a VA medical facility. Sufficient data to make an informed determination will be made available to such next-of-kin. If the patient's next-of-kin is not reasonably accessible, the Chief of Staff, Director, or designee of the custodial VA medical facility may disclose the information for these purposes.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored electronically on a VA server, in paper folders, magnetic discs, magnetic tape, and in a momentum cloud application. Paper documents may be scanned/digitized and stored for viewing electronically.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Alphabetically by name and numerically by identification number. Access to the records is restricted to VA Finance employees. These records are protected from outside access by Federal Protective Service.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Individuals Submitting Invoices-Vouchers for Payment and Accounting Transactional Data-VA system of records is retained as defined by its NARA approved the General Records Schedule (GRS) GRS 1.1: Financial Management and Reporting Records, item 010. Unscheduled records within this System of Records are indefinitely retained within the rules GRS, ERA Number DAA–GRS–2013–0003–0001 (Financial transaction records). Per NARA practice, documentation for permanent electronic records must be transferred with the related records using the disposition authority of the related electronic records rather than the GRS disposition authority.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

VA will store records produced within this system of records in an area that is physically and technologically secure from access by unauthorized persons at all times. Only authorized personnel will transport records within this system of records. VA will process records produced within this system of records under immediate supervision and control of authorized personnel in a manner that will protect the confidentiality of the records, so that unauthorized persons cannot retrieve any records by computer, remote terminal, or other means. VA will store records using FIPS 140–2 compliant encryption. Systems personnel must enter personal identification numbers when accessing records on the agencies' systems. VA will strictly limit authorization to those electronic records areas necessary for the authorized analyst to perform his or her official duties.

RECORD ACCESS PROCEDURES:

An individual wanting notification or access, including contesting the record, should mail or deliver a request to the office identified in the SORN. If an individual does not know the ''office concerned,'' the request may be addressed to the following with below requirements: PO or FOIA/PO of any VA field station or the Department of Veterans Affairs Central Office, 810 Vermont Avenue NW, Washington, DC 20420. The receiving office must promptly forward the mail request received to the office of jurisdiction clearly identifying it as ''Privacy Act Request'' and notify the requester of the referral. Approved VA authorization forms may be provided to individuals for use.

CONTESTING RECORD PROCEDURES:

An individual may request amendment of a record pertaining to him or her contained in a specific VA system of records by mailing or delivering the request to the office concerned. The request must be in writing and must conform to the following requirements: It must state the nature of the information in the record the individual believes to be inaccurate, irrelevant, untimely, or incomplete; why the record should be changed; and the amendment desired. The requester must be advised of the title and address of the VA official who can assist in preparing the request to amend the record if assistance is desired. Not later than business 10 days after the date of a request to amend a record, the VA official concerned will acknowledge in writing such receipt. If a determination for correction or amendment has not been made, the acknowledgement will inform the individual of when to expect information regarding the action taken on the request. VA will complete a review of the request to amend or correct a record within 30 business days of the date of receipt. Where VA agrees with the individual's request to amend his or her record(s), the requirements of 5 U.S.C. 552a(d) will be followed. The

record(s) will be corrected promptly, and the individual will be advised promptly of the correction.

If the record has previously been disclosed to any person or agency, and an accounting of the disclosure was made, prior recipients of the record will be informed of the correction. An approved VA notification of amendment form letter may be used for this purpose. An individual wanting notification or access, including contesting the record, should mail or deliver a request to the Privacy Office or FOIA/Privacy Office of any VA field station or the Department of Veterans Affairs Central Office, 810 Vermont Avenue NW, Washington, DC 20420.

NOTIFICATION PROCEDURES:

Notification for correcting the information will be accomplished by informing the individual to whom the record pertains by mail. The individual making the amendment must be advised in writing that the record has been amended and provided with a copy of the amended record. System Manager for the concerned VA system of records, Privacy Officer, or their designee, will notify the relevant persons or organizations who had previously received the record about the amendment.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

N/A

HISTORY:

Last full publication provided in 85 FR 22788 dated April 23, 2020.

[FR Doc. 2023–18807 Filed 8–30–23; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 437, and 457

Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 437, and 457

[CMS–2440–F]

RIN 0938–AU52

Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This document establishes requirements for mandatory annual State reporting of the Core Set of Children's Health Care Quality Measures for Medicaid and the Children's Health Insurance Program (CHIP), the behavioral health measures on the Core Set of Adult Health Care Quality Measures for Medicaid, and the Core Sets of Health Home Quality Measures for Medicaid.

DATES:

Effective Date: These regulations are effective January 1, 2024.

Applicability Date: The initial round (2024) of Core Sets reporting must be submitted and certified by States by December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Virginia Raney, (410) 786–6117, Children and Adults Health Care Quality Measurement.

Sara Rhoades, (410) 786–4484, Health Home Quality Measurement.

Candace Anderson, (410) 786–1553, Health Care Quality Measurement for Dually Eligible (Medicaid and Medicare) Beneficiaries.

SUPPLEMENTARY INFORMATION:

I. Background

A. Quality Measurement in Medicaid and CHIP

Medicaid was enacted in 1965 as Title XIX of the Social Security Act (the Act) to provide health coverage for certain groups of people with lower incomes. In 1997, upon enactment of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted August 5, 1997), the Children's Health Insurance Program (CHIP) was enacted as Title XXI of the Act. Combined, as of April 2023, the two programs provided health coverage to more than 94 million people, nearly half of whom are children (more than 42 million).[1]

Given the significant role that Medicaid and CHIP play in America's health care system, this rule requires—for the first time—States, the District of Columbia (DC) and certain territories to mandatorily report on measures of the quality of health care provided to Medicaid and CHIP beneficiaries.

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3, enacted February 4, 2009), established Federal requirements regarding voluntary quality measurement to assess the care delivered to beneficiaries in both Medicaid and CHIP.

Section 401 of CHIPRA added new section 1139A to the Act, which required development of a Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set), which could be voluntarily reported by States, and directed the Secretary to publish for general comment an initial recommended core set of child health quality measures based on existing quality of care measures for children not later than January 1, 2010. To assist the Federal Government in establishing priorities for the development and advancement of the Child Core Set, section 1139A of the Act also directed the Secretary to consult with a variety of specific interested parties in developing the initial measures and to work with interested parties annually to update the measures. CMS released the initial Child Core Set, consisting of 24 measures, in 2009, with voluntary State-level reporting beginning in Federal Fiscal Year (FFY) 2010.[2]

Section 2701 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted March 23, 2010) as amended and revised by the Healthcare and Education Reconciliation Act (Pub. L. 111–152, enacted March 30, 2010), referred to collectively as the Affordable Care Act (ACA), added a new section 1139B of the Act, extending the measurement of health care quality to Medicaid-eligible adults. While not required by statute, including separate CHIP enrollees in reporting on the Adult Core Set measures is encouraged; therefore, both Medicaid and CHIP populations are referenced in descriptions of the Adult Core Set (see additional discussion in section II.E. of the proposed rule). CMS issued the initial Adult Core Set consisting of 26 quality measures in 2012, and voluntary reporting of these measures began in FFY 2013.[3]

This rule implements mandatory annual reporting of the Child Core Set and the behavioral health measures on the Adult Core Set using a standardized format, as required by section 50102 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) and section 5001 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), (Pub. L. 115–271, enacted October 24, 2018).

B. Quality Measurement of the Medicaid Health Home Benefits Under Sections 1945 and 1945A of the Act

In addition to requiring reporting on the Child Core Set and specified behavioral health measures on the Adult Core Set, this rule establishes reporting requirements for States that elect to implement one or both of the optional Medicaid health home benefits under sections 1945 or 1945A of the Act. Section 1945 of the Act (added by section 2703 of the ACA and later amended by section 1006(a) of the SUPPORT Act) and section 1945A of the Act (added by section 3 of the Medicaid Services Investment and Accountability Act of 2019)[4] give States options for implementing two different Medicaid health home State plan benefits. The section 1945 health home benefit is for Medicaid-eligible individuals who have (1) two or more chronic conditions, as defined in section 1945(h)(2) of the Act, (2) at least one chronic condition, as defined in section 1945(h)(2) of the Act, and who are at risk for a second, or (3) at least one serious and persistent mental health condition.[5] The section 1945A health home benefit is for Medicaid-eligible children with medically complex conditions, as defined in section 1945A(i)(1) of the Act.[6] States were able to begin covering the section 1945 health home benefit on

[1] February 2023 Medicaid and CHIP Enrollment data: *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/april-2023-medicaid-chip-enrollment-trend-snapshot.pdf.*

[2] Initial Child Core Set: *https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO11001.pdf.*

[3] Initial Adult Core Set: *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib-01-04-12.pdf.*

[4] Public Law 116–16, enacted April 18, 2019.

[5] On November 16, 2010, we issued State Medicaid Director (SMD) letter #10–024, which provided States with guidance on implementing the section 1945 health home benefit. See *https://www.medicaid.gov/federal-policy-guidance/downloads/SMD10024.pdf.*

[6] On August 1, 2022, we issued SMD letter #22–004, which provides States with guidance on implementing the section 1945A health home benefit. See *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22004.pdf.*

January 1, 2011. States were able to begin covering the section 1945A health home benefit on October 1, 2022.

As a condition for receiving payment for section 1945 health home services, section 1945(g) of the Act requires section 1945 health home providers to report to the State, in accordance with such requirements as the Secretary shall specify, on all applicable measures for determining the quality of health home services. Section 1945(c)(4)(B) of the Act also requires certain States with an approved substance use disorder (SUD)-focused section 1945 health home State plan amendment (SPA) to report information to the Secretary on certain topics, including on the quality of health care provided to SUD-eligible individuals receiving health home services under the SUD-focused health home SPA.[7] Section 1945(c)(4)(B) of the Act further provides that the Secretary shall specify all applicable quality measures that would be included in the reporting required under that provision. Per section 1945(c)(4)(B) of the Act, States must submit the required report at the end of the period of such SPA. We have interpreted this language to mean that the report should provide data relating to the enhanced Federal medical assistance percentage (FMAP) period available to the State under section 1945(c)(4) of the Act and that States should submit the report within 6 months after the enhanced FMAP period ends.[8]

[7] Center for Medicaid and CHIP Services (CMCS) Informational Bulletin, ''New Reporting Measures for Substance Use Disorder (SUD)-focused Health Homes,'' November 27, 2019, at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib112719.pdf*.

[8] Under section 1945(c)(1) of the Act, State payments for section 1945 health home services provided during the first 8 fiscal year quarters that a section 1945 SPA is in effect are Federally matched at a 90 percent Federal Medical Assistance Percentage (FMAP). Section 1006(a) of the SUPPORT Act, ''Extension of Enhanced FMAP for Certain Health Homes for Individuals with Substance Use Disorders,'' amended section 1945(c) of the Act to permit an extension of this period of 90 percent FMAP for certain section 1945 health home SPAs for individuals with substance use disorders (SUD) for two additional quarters (such that there could be a total of 10 quarters for the 90 percent FMAP). CMS provided guidance to States about this amendment to section 1945 in a May 7, 2019, Center for Medicaid and CHIP Services (CMCS) Informational Bulletin (CIB), ''Guidance for States on the Availability of an Extension of the Enhanced Federal Medical Assistance Percentage (FMAP) Period for Certain Medicaid Health Homes for Individuals with Substance Use Disorders (SUD),'' *https://www.medicaid.gov/federal-policy-guidance/downloads/cib050719.pdf*. We released further guidance on the section 1945(c)(4)(B) reporting requirements in a CIB entitled ''New Reporting Measures for Substance Use Disorder (SUD)-Focused Health Homes'' on November 27, 2019, *https://www.medicaid.gov/federal-policy-guidance/downloads/cib112719.pdf*.

Apart from the one-time-only required report under section 1945(c)(4)(B) of the Act, section 1945 of the Act does not require States to submit quality measure reporting to CMS or the Secretary related to the section 1945 health home benefit. However, since 2013, we have encouraged States (including States subject to the one-time-only report specified at section 1945(c)(4)(B) of the Act) to report annually on a set of section 1945 health home quality measures (section 1945 Health Home Core Set).[9] We published an initial core set of section 1945 health home quality measures in 2013, with updates issued annually. We also explained when publishing the initial core set of section 1945 health home quality measures that reporting on the section 1945 Health Home Core Set would be *voluntary* until regulations were promulgated to require it. However, to ease the reporting burden, all but one of the recommended measures was aligned with measures in the Adult Core Set.[10] Subsequent updates to the section 1945 Health Home Core Set have been made on an annual basis. In developing and updating the section 1945 Health Home Core Set, we have generally tried to align it with the Child and Adult Core Sets. In November 2019, we released a Center for Medicaid and CHIP Services (CMCS) Informational Bulletin (CIB), which added two additional measures specific to SUD-focused health home programs to the 2020 section 1945 Health Home Core Set on which States could consider reporting as part of the required reporting under section 1945(c)(4)(B) of the Act.[11]

Section 1945A(g)(1)(B) of the Act requires section 1945A health home providers to report information to the State on all applicable measures for determining the quality of health home services provided by the provider, including, to the extent applicable, child health quality measures and measures for centers of excellence for children with complex needs developed under Title XIX, Title XXI, and section 1139A of the Act (which would include the Child Core Set). Additionally, unlike section 1945 of the Act, which requires States to report on quality measures to the Secretary only if the State is subject to section 1945(c)(4)(B) of the Act, section 1945A of the Act requires all States implementing that benefit to submit reports to the Secretary on a range of topics. Under section 1945A(g)(2)(A)(i) of the Act, these reports must include all information reported by providers to the State under section 1945A(g)(1) of the Act, including the quality measure reporting required under section 1945A(g)(1)(B) of the Act. We interpret the language in section 1945A(g)(2)(A)(i) of the Act to refer to reporting on core measures developed for purposes of evaluating the quality of section 1945A health home services, because that provision cross-references the language in section 1945A(g)(1)(B) of the Act that mentions quality measures developed under various provisions of the Act, including the Child Core Set.

This rule establishes the following requirements for States electing to implement the benefit under sections 1945 or 1945A of the Act. Under the provisions of this rule, States that have implemented the section 1945 and/or 1945A health home benefit must report annually on the mandatory measures in the section 1945 Health Home Core Set and/or a proposed section 1945A Health Home Core Set (depending on which of the two benefits the State has opted to cover) and must require their health home providers to report to the State on those measures. Annual CMS reporting guidance will provide information on specific measures for which reporting is mandatory for the section 1945 and section 1945A Health Home Core Sets (including any specific measures that would be mandatory for States with a SUD-focused section 1945 health home). For States covering the section 1945 health home benefit, this requirement is based on section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. For measures specific to States with SUD-focused health home SPAs subject to section 1945(c)(4)(B) of the Act, this requirement is also authorized by the language in section 1945(c)(4)(B) of the Act stating that the Secretary shall specify all applicable measures for determining quality for purposes of section 1945(c)(4)(B) of the Act, but this rule does not otherwise address the reporting requirements under section 1945(c)(4)(B) of the Act. Requiring States to require their section 1945 health home providers to report to the State on the Health Home Core Set is further supported by the language in

[9] SUD Health Home reporting CIB at *https://www.medicaid.gov/Federal-policy-guidance/downloads/cib112719.pdf*.

[10] Initial section 1945 Health Home Core Set: *https://www.medicaid.gov/federal-policy-guidance/downloads/smd-13-001.pdf*.

[11] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib112719.pdf*.

section 1945(g) of the Act providing that section 1945 health home providers shall report to States on all applicable measures for determining the quality of section 1945 health home services, in accordance with such requirements as the Secretary shall specify. For States covering the section 1945A health home benefit, these requirements are authorized by section 1945A(g)(1) and (2) of the Act (see discussion of those provisions above), as well as by section 1902(a)(6) of the Act. While this rule implements section 1945A(g)(2)(A)(i) of the Act, section 1945A(g)(2)(A) of the Act requires States to report to the Secretary on several additional topics that are not addressed in this rule. CMS expects to provide information to States about the rest of the reporting requirements under section 1945A(g)(2)(A) of the Act in the future.

C. Building a System of Reporting To Improve the Quality of Care Delivered

Implementation of the Child and Adult Core Sets, and the sections 1945 and 1945A Health Home Core Sets, represents a major step in the development of a national, evidence-based system for measuring and improving the quality of care delivered to Medicaid and CHIP beneficiaries. The Core Sets include measures that, taken together, may be used to estimate the overall national quality of health care provided to beneficiaries. The ability to assess the quality of and access to care furnished by State Medicaid and CHIP programs is critical given that more than 93 million Americans receive coverage in Medicaid and CHIP, and the annual expenditures for the programs are over $600 billion.[12]

1. Development of Core Sets

To ensure that the measures included in the Child and Adult Core Sets reflect the needs of Medicaid and CHIP beneficiaries and provide the types of information necessary to assess the overall national quality of health care, sections 1139A and 1139B of the Act establish a number of specific parameters for the development of these core sets. For a complete and full description of these requirements see sections 1139A and 1139B of the Act.

The initial section 1945 Health Home Core Set was established in 2013 as a recommended set of health care quality measures for assessing the section 1945 health home service delivery model. We have updated the section 1945 Health Home Core Set annually since 2013, and in 2021 we established a Health Home Annual Review Workgroup to align this update process with the CMS process to annually update the Child and Adult Core Sets (as further discussed below).

We formed a joint Child and Adult Core Sets Annual Review Workgroup in 2019, consolidating what had previously been two separate workgroups, to implement the statutory requirements and to ensure that measures in the Core Sets are meaningful for States and interested parties and feasible for State-level reporting.[13] In 2021, the Health Home Annual Review Workgroup was implemented, following the same structure and guidelines as the workgroup for the Child and Adult Core Sets, to develop and update section 1945 and section 1945A Health Home Core Sets. The joint Child and Adult Core Sets Annual Review Workgroup and the Health Home Annual Review Workgroup (''Workgroups'') develop recommendations on how to revise, strengthen, and improve the applicable Core Sets measures, and every year the Workgroups' recommended changes are published for public comment and then submitted to CMS. All meetings are open to the public, and public comment is invited during each meeting.

D. Shifting From Voluntary to Mandatory Reporting

In 2018, Congress passed two laws that mandate State reporting of the Child Core Set and the behavioral health measures on the Adult Core Set. These laws help address the limitations of voluntary reporting and significantly strengthen the ability of the Core Sets to drive quality improvements for Medicaid and CHIP beneficiaries nationwide.

First, section 50102(b) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) added a new subparagraph (B) to section 1139A(a)(4) of the Act to mandate annual reporting of the Child Core Set beginning with the annual State report on FFY 2024. Specifically, section 1139A(a)(4)(B) of the Act provides that beginning with the annual State report on FFY 2024, the Secretary shall require States to use the initial core measurement set and any updates or changes to that set to report information regarding the quality of pediatric health care under titles XIX and XXI. Additionally, section 1139A(a)(4)(B) of the Act requires, once mandatory reporting begins, that States submit such information using the standardized format for reporting information and procedures developed by CMS in consultation with States in accordance with section 1139A(a)(4)(A) of the Act.

Second, section 5001 of the SUPPORT Act (Pub. L. 115–271, enacted October 24, 2018), added a new subparagraph (B) to section 1139B(b)(3), to make mandatory the annual reporting of behavioral health measures in the Adult Core Set. The SUPPORT Act requirement also becomes effective beginning with the annual State report on FFY 2024. Per section 1139B(b)(3)(B) of the Act, States are required to report on all behavioral health measures included in the core set of adult health quality measures and any updates or changes to such measures, and as with the Child Core Set, reporting of the behavioral health measures must be submitted using the standardized format for reporting information and procedures developed by CMS in consultation with States.

As discussed previously, this final rule also implements certain statutory requirements in sections 1902(a)(6), 1945, and 1945A of the Act to require States that have opted to implement the section 1945 or section 1945A health home benefit to report on the section 1945 or 1945A Core Sets, as applicable, and also to require their health home providers to report on the applicable health home core set.

II. Summary of the Proposed Provisions and Analysis of and Responses to the Public Comments

We received 93 public comments from individuals and organizations, including, but not limited to, State government agencies, non-profit health care organizations, advocacy groups, associations, law firms, managed care organizations, academic groups, tribal organizations, and private citizens. We thank the commenters for their consideration of the proposed requirements for mandatory reporting and appreciate the submission of all of the comments received. In general, commenters supported the proposed rule. In this section, arranged by subject area, we summarize the proposed provisions, the public comments received, and our responses. For a complete and full description of the proposed mandatory reporting requirements, see the 2022 proposed rule, ''Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting'' (87 FR 51303, August 22,

[12] January 2023 Medicaid and CHIP Enrollment data: *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/january-2023-medicaid-chip-enrollment-trend-snapshot.pdf;* and *https://www.medicaid.gov/state-overviews/scorecard/annual-medicaid-chip-expenditures/index.html.*

[13] Annual Review and Selection Process: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/annual-core-set-review.pdf.*

2022) hereafter referred to as the ''proposed rule''.

A. Basis, Scope, Purpose and Applicability

As discussed in section II.A. of the proposed rule, we proposed in § 437.1 to specify the basis and scope of the proposed requirements and to establish the purpose of the Child Core Set, Adult Core Set, and the Health Home Core Sets. We also proposed in § 437.10 to implement a process through which we would develop and update the Child Core Set, Adult Core Set, and the Health Home Core Sets (sections 1945 and 1945A) and proposed in § 437.10 the process through which we would establish requirements that State agencies would have to meet when reporting on the measures included in these Core Sets. We also proposed in §§ 437.10 and 437.15 the form, reporting, time, and manner requirements for reporting the Core Sets. We proposed that the requirements for Child and Adult Core Sets reporting would apply to the 50 States, DC, Puerto Rico, the Virgin Islands, and Guam; and throughout the rule the term ''States'' is used to collectively refer to these States and territories when we are referring to the Child and Adult Core Sets. American Samoa and the Mariana Islands could, but would not be required to, report Child and Adult Core Set measures. We also proposed requirements for State reporting of health home quality measures in §§ 437.10 and 437.15 and noted the Secretary has the authority under sections 1945(g) and 1945A(g) of the Act to require States to require their health home providers to report on the Home Health Core Sets measures. The requirement for reporting on one or both of the Health Home Core Sets would apply to any State (as defined under section 1101 of the Act for purposes of Title XIX) with an approved Medicaid Health Home SPA under section 1945 or 1945A of the Act. We also proposed, in § 437.15(a)(1), to set the deadline to meet these requirements for State reporting on the 2024 Core Sets as no later than December 31, 2024.

In general, commenters who submitted public comments on the proposed general requirements for mandatory reporting supported the proposed scope, purpose, and process. We are finalizing those provisions in §§ 437.1, 437.10 and 437.15 with revisions to § 437.10 to specify timelines for Child and Adult Core Sets updates and timelines for CMS reporting of Child and Adult Core Sets data. We added § 437.15(a)(1)(i) to specify timelines for the first year of mandatory reporting of the Child Core Set and behavioral health measures on the Adult Core Set. The addition of this new provision shifted the numbering of the remainder of the provisions in § 437.15(a)(1), redesignating § 437.15(a)(1)(i) to § 437.15(a)(1)(ii), etc. We also edited § 437.15(a)(1)(iv), originally proposed as § 437.15(a)(1)(iii), to include only the measures on the Adult Core Set that are not included in § 437.15(a)(1)(i) and (ii) as optional for states to report, removing the reference to the Health Home Core Sets to align with changes in other sections. Below is a summary of the public comments we received related to the scope, purpose, and applicability of the requirements as proposed and our responses.

Comment: Several commenters supported the proposed rule in its entirety or specifically indicated their support for reporting of a specific component such as the behavioral health measures on the Adult Core Set. Many of the comments referred to the positive outcomes that CMS expects from finalization of these proposals. The commenters generally expressed support for these proposals and noted that the proposed changes to the requirements for reporting the Core Sets will support the improvement of health outcomes for Medicaid and CHIP beneficiaries overall in addition to addressing health disparities and inequities.

Response: We appreciate the support for our proposal and thank those who took the time to give us feedback.

Comment: Several commenters recommended the following revisions (indicated below in bold typeface) to the proposed § 437.1(c)(1): ''The purpose of the Medicaid and CHIP Child Core Set and the Medicaid Adult Core Set is to measure the overall national quality of care for beneficiaries; **monitor performance and promote comparative analysis at multiple levels, including the State, program, plan and provider levels; and eliminate health disparities across populations;** and improve the quality of health care.'' They cite the following statutes:

- Section 1139A(a)(8) of the Act to support the definition of the Child Core Set as a ''group of valid, reliable, and evidence-based quality measures.''
- Section 1139A(b) of the Act established the Pediatric Quality Measures program to advance the development of evidence-based quality measures for children which, per sections 1139A(b)(2)(B) and (C) of the Act, ''shall, at a minimum, be . . . designed to identify and eliminate racial and ethnic disparities in child health and the provision of health care'' and ''ensure that the data required for such measures is collected and reported in a standard format that permits comparison of quality and data at a State, plan, and provider level.''
- Section 1139A(a)(3)(D) of the Act to highlight health disparities and comparative analysis in its requirement that the initial Child Core Set ''taken together, can be used to estimate the overall national quality of health care for children, including children with special needs, and to perform comparative analyses of pediatric health care quality and racial, ethnic, and socioeconomic disparities in child health and health care for children.''
- Sections 1139B(a) and (b)(5) of the Act that direct the Secretary to develop the Adult Core Set ''in the same manner'' as the Child Core Set.

Response: We appreciate the suggestion to revise this section of the regulation and agree with the commenters on the importance of aligning quality measurement across multiple levels and measure sets, as feasibility and applicability allow. We consider measuring and reporting health disparities to be a cornerstone of CMS' approach to advancing health equity and improving quality as outlined in the proposed rule. The public comment recommending that the purpose of the Child and Adult Core Sets include ''comparison of quality and data at a State, program, plan, and provider level'' cites the statutory requirement as section 1139A(b)(2)(C) of the Act. That statutory requirement applies to measures developed under the pediatric quality measures program and does not refer to the reporting requirements for the Child Core Set, which are established in section 1139A(c) of the Act and require ''Annual State Reports Regarding State-Specific Quality of Care Measures Applied Under Medicaid or Chip.'' Section 1139A(c) of the Act requires reporting of State-level Child Core Set data, and does not require program-, plan- or provider-level reporting. In addition, it does not necessarily require comparative analysis of such data. There is similar language in section 1139B(d) of the Act, which requires reporting of Adult Core Set data at the State-level. Given these considerations, we are finalizing § 437.1(c)(1) as proposed, with the purpose of the Medicaid and CHIP Child Core Set and the Medicaid Adult Core Set to measure the overall national quality of care for beneficiaries, monitor performance at the State-level, and improve the quality of health care.

Comment: Several commenters recommended that CMS add a provision to the final rule to require CMS to

collect, analyze, and make publicly available Child and Adult Core Sets data annually by September 30th. Other commenters recommended that CMS add a provision to the final rule to require CMS to publish recommended changes to the Child and Adult Core Set measures by January 1 of each year.

Response: The statutory authority for the Core Sets at sections 1139A(c)(2) and 1139B(d)(2) of the Act requires the Secretary to collect, analyze, and make publicly available, by September 30th of each year, the information reported in the annual State reports described in sections 1139A(c)(1) and 1139B(d)(1) of the Act. Similarly, sections 1139A(b)(5) and 1139B(b)(5)(B) of the Act require the Secretary to publish recommended changes to the Child and Adult Core Sets by January 1st annually. We have historically followed this timeline for updating Core Sets. To address the recommendations received in public comments regarding the Child and Adult Core Sets to add these provisions to the final rule, we added these requirements at § 437.10(a)(1) and (4). Although the comment is not specific to Health Home Core Sets, we are specifying at § 437.10(a)(5) that the Secretary shall collect, analyze, and make publicly available data from the Health Home Core Sets annually.

Comment: One commenter recommended that because most of the current Health Home Core Sets measures have continuous enrollment periods of ''no gaps in coverage,'' ''no more than 45-day gap in coverage,'' and ''no more than 90-day gap in coverage,'' CMS should alter § 437.15(a)(1)(ii) in the proposed rule from ''the applicable health home program has an effective date and has been implemented more than 6 months prior to the December 31st reporting deadline'' to ''. . . implemented for nine or more months . . .''

Response: In an effort to include as many active health home programs as possible in quality measurement reporting, we believe it is preferable to maintain the minimum requirement as it was proposed, even if this means a health home program may lack sufficient data to report on certain measures, as what a health home program can report will still be useful to help us and the State to understand the quality of care provided in the health home program. Specifically, the requirement states that a health home program must report if it has been implemented for more than 6 months prior to the December 31st reporting deadline. Therefore, we are finalizing the proposed § 437.15(a)(1)(ii) at § 437.15(a)(1)(iii) (to accommodate addition of a new provision at § 437.15(a)(1)(i), as discussed previously in this final rule) without other changes.

Comment: A few commenters expressed support for the proposed changes but provided feedback on areas that were not addressed in the proposed rule. One commenter noted that it is critical that health plans reporting on Core Set quality measures have effective tools to communicate with enrollees in order to ensure that enrollees understand plan benefits and recommended health care screenings and services, and that these plans can also address barriers to higher quality care. This commenter requested that CMS issue guidance to States to help improve communication with beneficiaries due to confusion regarding the Telephone Consumer Protection Act (TCPA) (Pub. L. 102–243, enacted December 20, 1991). Another commenter recommended that CMS work with State Medicaid programs to remove undue pharmacy scope of practice restrictions, and to adopt payment pathways that recognize pharmacists as eligible providers and enable pharmacies to provide and be reimbursed for clinical care interventions that improve the health and wellbeing of beneficiaries. Another commenter suggested CMS consider a pilot to apply the pediatric measures to all payers, starting with States with all-payer claims databases as this would help demonstrate the impact of different interventions on children's health more broadly and may address some of the ''small numbers'' challenges when looking at subgroups of children, such as children with special health care needs. Lastly, one commenter recommended the development of national standards for assessing access to Medicaid and CHIP services to include at minimum: time and distance standards, coverage of reimbursement for a variety of health care services, and consistent standards across fee-for-service (FFS) and managed care.

Response: We thank the commenters for their support of the proposed requirements for mandatory reporting and appreciate the submission of these comments but note that these areas are outside of the scope of this rulemaking.

Comment: One commenter requested confirmation that States with section 1115 demonstrations are included in mandatory reporting.

Response: States are required to report mandatory Core Set measures for all required populations, even if those beneficiaries are enrolled in a section 1115 demonstration. States with section 1115 demonstrations are required under demonstration Special Terms and Conditions (STCs) to monitor their demonstration's performance. Section 1115 demonstration monitoring and reporting requirements are in addition to and not in lieu of requirements for State-level Core Set reporting as outlined in this final rule. As part of the demonstration monitoring process, we may require that States report a select set of Core Set measures that support assessing performance and progress toward specific goals and objectives of the demonstration. This reporting, which may be adapted for demonstration populations, is in addition to mandatory Core Set reporting. Additionally, States may leverage Core Set measures as part of their section 1115 demonstration evaluation.

Comment: Several commenters recommended that CMS streamline the language in § 437.15(a) to remove references to the specific sets of measures (that is, the Child Core Set or behavioral health measures on the Adult Core Set) that will become mandatory under this final rule as redundant, noting that section 1139B of the Act does not preclude CMS from using its authority under section 1902(a)(4) of the Act to require reporting on additional measures if necessary to ensure the proper and efficient administration of the Medicaid program. Other commenters encouraged CMS to consider its independent authority, outside of sections 1139A and 1139B of the Act to require mandatory reporting of additional measures to advance quality in Medicaid through section 1902(a)(6) of the Act.

Response: We believe the Congressional intent is for mandatory reporting to apply to the Child Core Set and the behavioral health measures of the Adult Core Set, and not to apply to the remaining quality measures. For the Child and Adult Core Sets, this rulemaking is not proposing to make mandatory any measures beyond those under sections 1139A and 1139B of the Act. Therefore, we are maintaining the proposed scope of mandatory reporting and are not making any changes to § 437.15(a) in response to this comment.

Comment: One commenter urged CMS to consider ways to help address any burden that new data collection efforts may cause for States by exploring funding opportunities to assist States in conducting the necessary activities to implement these important provisions effectively.

Response: We appreciate the submission of this comment but note that this issue is outside of the scope of this rulemaking. As noted in the proposed rule, in Medicaid, enhanced

Federal Financial Participation (FFP) is available at 90 percent for the design, development, and installation (including of enhancements) of mechanized claims processing and information retrieval systems, and 75 percent enhanced FFP is available for operations of such systems, in accordance with applicable Federal requirements.[14] Receipt of these enhanced Federal Medicaid matching rates is conditioned upon States meeting a series of standards and conditions.[15] Additionally, under section 1903(a)(3)(A)(iii) of the Act, the FFP for State expenditures on systems development or modifications necessary for efficient collection and reporting on the Child Core Set is at the State's FMAP under section 1905(b) of the Act. We also note that under section 1903(a)(7) of the Act, Federal Medicaid matching funds may be available at a 50 percent Federal match rate for staffing and contracting related to implementing Core Set reporting requirements, as these activities might, subject to certain conditions, be necessary for the proper and efficient administration of the State plan. To the extent these system expenditures are attributable to a State's CHIP (Medicaid Expansion CHIP (MCHIP), or separate CHIP), cost-allocation methodologies set forth in 45 CFR part 75 apply. For the CHIP-funded portion of the expenditure, States can claim at a State's CHIP enhanced FMAP (eFMAP) available under section 2105(b) of the Act. We note that systems expenditures are administrative expenditures, and CHIP administrative funding is limited to 10 percent of either a State's total computable allotments for a FFY or its total expenditures reported for a FFY, whichever is lower.[16]

B. Definitions

As discussed in section II.B. of the proposed rule, in § 437.5 we proposed the definitions related to quality measurement and reporting. Commenters generally supported the proposed definitions, and we are finalizing these provisions with a revision to the definition of behavioral health in § 437.5 and other minor wording changes to clarify cross-references within the same subpart. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters recommended that CMS revise (with revisions indicated in boldface type below) the definition of ''behavioral health'' proposed at § 437.5: ''Behavioral health means a beneficiary's whole emotional and mental well-being, which includes, but is not limited to, the prevention, treatment **and recovery** from mental disorders **and** substance use disorders.'' The commenters recommended adding ''and recovery'' to the meaning of behavioral health and replace ''including'' with ''and'' regarding the inclusion of substance use disorders in this definition.

Response: We agree with the recommendation to add ''and recovery,'' as recovery is a key part of improving the health outcomes for individuals with behavioral health conditions, and are revising the definition of behavioral health in § 437.5 of this final rule.[17] Regarding the second suggestion, we will retain the language as originally proposed, ''mental disorders including substance use disorders,'' as that aligns with the American Psychiatric Association's position, reflected in the Diagnostic and Statistical Manual of Mental Disorders (DSM–5), that substance use disorders are included in the definition of mental disorders.

Comment: Several commenters supported CMS' proposal to broadly define ''behavioral health'' and ''behavioral health measures.'' Some commenters recommended additional guidance on the potential scope of conditions and quality measures included in the definition to ensure a shared understanding of such definitions and help prepare for reporting.

Response: We appreciate the support for the proposed ''behavioral health'' definition, which aligns with the behavioral health conditions included in the American Psychiatric Association's DSM–5. We plan to use the DSM–5 as a resource in determining which measures on the Adult Core Set should be considered behavioral health measures and thus subject to mandatory reporting requirements and will specify these measures in annual reporting guidance. In November 2022, we issued the annual CIB updating the Core Sets, the 2023–2024 Core Sets measure lists, to include a subset of measures identified as the Behavioral Health Core Set, which includes all the behavioral health measures on the Adult Core Set.[18] [19] As noted, we are finalizing the definition in § 437.5 with one revision, to add ''and recovery.''

C. The Child, Adult, and Health Home Core Sets

As discussed in section II.C. of the proposed rule, in § 437.10 we proposed to continue the existing annual process of identifying and updating the measures comprising the Child, Adult, and Health Home Core Sets through annual consultation with States and other interested parties to establish priorities for the development and advancement of the Child, Adult, and both Health Home Core Sets. We proposed in § 437.10(a)(2) to identify any gaps in the measures included in each Core Set; to identify measures which should be removed because they no longer strengthened the Core Sets; and to ensure that all measures included in the Core Sets would reflect an evidence-based process (including testing, validation, and consensus among interested parties). The measure(s) selected would be meaningful for States and feasible for State-level and/or health-home program level reporting, as appropriate.

Commenters generally supported the process proposed in § 437.10(a) and (e) by which we would update the Core Sets and publicly report data on such measures. Commenters also asked several questions about specific measures on the Core sets. We will be finalizing these provisions in this final rule with a revision to § 437.10(a)(iv), where we describe measure criteria for the Core Sets, and with revisions to §§ 437.10(b) and 437.15(a), where we have provided additional detail on reporting requirements, and we discuss these changes further in sections II.D.2. and II.D.3. of this final rule. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters provided feedback on areas that were not addressed in the proposed rule such as: proposing specific changes to the Core Sets, proposing measure additions or removals, identifying measure gaps on the Core Sets, adding non-behavioral health measures to the list of Adult Core Set measures required in mandatory reporting, and measure development and testing. Specifically, a few commenters recommended a ''duration of coverage'' measure as called for by existing statute (section 1139A(a)(3)(A) of the Act) to assess the negative impact of churn on the quality of care that children receive and recommended that this measure be added to the Child Core Set no later than mandatory reporting for 2024.

[14] See section 1903(a)(3)(A)(i) and (B) of the Act, § 433.15(b)(3) and (4), and subpart C of 42 CFR part 433.

[15] 42 CFR 433.112 and 42 CFR 433.116.

[16] See 42 CFR 457.618(e)(1).

[17] CMS Behavioral Health Strategy: *https://www.cms.gov/cms-behavioral-health-strategy.*

[18] 2022 Core Set CIB: *https://www.medicaid.gov/sites/default/files/2022-11/cib111522_0.pdf.*

[19] 2023–2024 Behavioral Health Core Set: *https://www.medicaid.gov/sites/default/files/2022-11/2023-bh-core-set.pdf.*

Response: We appreciate the submission of these comments, and we will consider these comments as part of the measure adoption subregulatory process. We encourage the commenters to attend meetings of the joint Child and Adult Core Sets Annual Review Workgroup and the Health Home Annual Review Workgroup (Workgroups), which are convened annually to develop recommendations on how to revise, strengthen, and improve the applicable Core Sets measures.[20] All meetings are open to the public, public comment is invited during each meeting, and every year the Workgroup recommendations are published for public comment.[21]

We agree with the commenters regarding the importance of understanding the continuity of coverage among Medicaid and CHIP beneficiaries, recognizing that disruptions in coverage can lead to periods of uninsurance, delayed care, and reduced access to preventive care and other essential care for beneficiaries. Beneficiaries moving on and off Medicaid and CHIP coverage (sometimes called ''churning'') can lead to higher administrative costs, less predictable State expenditures, and higher monthly health care costs due to pent-up demand for health care services. To help address this issue, section 5112 of subtitle B of title V of division FF of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328), which was signed into law December 29, 2022, requires all States to provide 12 months of continuous eligibility for most children under the age of 19 in Medicaid and CHIP, effective January 1, 2024. There are no existing standardized quality measures in this area; however, we published a data brief in November 2022 on Medicaid and CHIP Access: Coverage and Behavioral Health Data Spotlight, which provides in depth data on continuity of coverage.[22] We will consider the best venue for continued reporting of these important metrics.

Comment: One commenter encouraged CMS to consider making the National Core Indicators Survey (NCIDD–AD) within the Adult Core Set a voluntary component, because they believe that there would be a low response rate to this survey, which is administered in person.

Response: While we appreciate the submission of this comment, the issue of which specific measures will be voluntary versus mandatory will be considered in the subregulatory measure revision process described previously in this final rule. The NCIDD–AD measure is an experience of care survey that was added to the Adult Core Set to address a gap in measures for long-term services and supports. It has not been identified as a behavioral health measure and will not become mandatory for State reporting in 2024. Measure administration and technical specifications are set by the measure steward, the National Association of State Directors of Developmental Disabilities Services and Human Services Research Institute.

Comment: One commenter encouraged CMS to work with States to ensure that contraceptive care measures are used appropriately in the Child Core Set without reference to an external benchmark that may suggest an appropriate level of contraceptive use, and without provider incentives that could promote forms of coercion.

Response: This comment is outside the scope of rulemaking. However, we appreciate this comment identifying potential issues related to the appropriate use and interpretation of the contraceptive care measure results. Specific to the Contraceptive Care measure, we note that we do not publish a benchmark for this measure, which examines provision of a most or moderately effective method of contraception and provision of a long-acting reversible method of contraception. The lack of benchmark reflects that some individuals will make informed decisions to choose methods in the lower tier of efficacy even when offered the full range of methods.[23] To help ensure that data users understand that the goal is not prescribing contraceptives to 100 percent of women, we include language in public reporting (that is, the Child Core Set Chart Pack) [24] indicating the estimated percentage in need of contraceptive services. Additionally, we cite resources from Office of Population Affairs (OPA) with language about the goal and guidance for how to interpret the measure.[25]

Comment: Several commenters recommended that CMS not use the Core Set data for State comparisons without accounting for State variation, including program and benefit design, geography and resources, and beneficiary characteristics.

Response: We appreciate the submission of these comments and will take this feedback into consideration when developing Core Set reporting guidance and materials for public reporting.

Comment: One commenter requested that the Secretary require managed care organizations (MCOs) to deliver stratified data in a timely manner to Federally Qualified Health Centers (FQHCs), facilities, and providers.

Response: While we appreciate the submission of this comment, this issue is outside the scope of this rulemaking.

Comment: Several commenters provided recommendations on our publication of Core Set data, including that CMS limit phasing-in the publication of State-level data to no more than 3 years; that CMS publish all State-level data even if not enough States have reported for CMS to conduct comparative analysis and to report quartile rankings; that CMS reconsider its policy to limit public reporting of voluntary Core Set measures to measures that are reported by at least 25 States; and that CMS publish standardized core measures data with national benchmarks that would permit comparisons across States and over time.

Response: We will continue to publish Core Set data annually, as required under sections 1139A(c)(2) and 1139B(d)(2) of the Act for the Child Core Set and the Adult Core Set, respectively. We have worked to find a balance in the reporting of State data that meets these statutory reporting requirements while taking into consideration data quality and the ability to conduct comparative analysis. We appreciate the submission of these comments and will take them into consideration as we review State data as well as for future policymaking.

Comment: Several commenters recommended that CMS seek to align the Core Set measures with other national reporting systems such as the Core Quality Measures Collaborative (CQMC) or the Medicaid and CHIP Quality Rating System (MAC QRS) in order to minimize additional reporting burden on providers and to ensure parsimony, alignment, harmonization, and the avoidance of competing quality measures. Other commenters noted that CMS should align with measures appropriate for State health care goals as defined by the National Committee for

[20] *https://www.medicaid.gov/medicaid/quality-of-care/downloads/annual-core-set-review-11102022.pdf.*

[21] *https://www.mathematica.org/features/maccoresetreview.*

[22] *https://www.medicaid.gov/medicaid/access-care/index.html.*

[23] *https://opa.hhs.gov/research-evaluation/title-x-services-research/contraceptive-care-measures.*

[24] Annual Reporting on the Child Core Set: *https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/childrens-health-care-quality-measures/index.html#AnnualReporting.*

[25] *https://opa.hhs.gov/sites/default/files/2020-07/interpreting-rates-for-contraceptive-care-measures.pdf.*

Quality Assurance (NCQA), National Quality Forum (NQF), and the Utilization Review Accreditation Commission (URAC).

Response: We agree with the commenters on the importance of parsimony, alignment and harmonization in quality measurement and will consider these comments for subsequent rulemaking. Throughout the annual Core Set review process, we facilitate measure alignment through engagement with a variety of internal and external interested parties, Federal partners, other reporting systems related to Medicaid and CHIP, and Medicare and Marketplace quality programs, as well as through initiatives such as the Universal Foundation, a set of quality measures around which programs at CMS are aligned.[26] In some cases, we may use different measures in order to capture quality at different levels of the health system, such as at the State level. Given that these processes are in place, we are not making changes to § 437.10(a) in response to these comments.

Comment: Several commenters stated that that the proposed language requiring consideration of regulatory burden would hinder CMS' ability to add new measures to the Core Sets and to require States to report measures by specific populations or demographic characteristics. They recommended amending the proposed § 437.10(a)(2)(iv) to delete the reference to burden to the States as follows (edits in bold): ''(iv) Ensure that all measures included in the Core Sets reflect an evidence-based process including testing, validation, and consensus among interested parties; are meaningful for States; **and** are feasible for State-level and/or Health Home program level reporting as appropriate.''

Response: We agree with this comment that this language is open to interpretation and therefore accept the suggestion to revise § 437.10(a)(2)(iv) to remove the language ''and represent minimal additional burden to States.'' The remaining language in the provision regarding feasibility will help to ensure that we will not overburden States when adding measures to the Core Sets, and we agree that the additional language about minimal additional burden may hinder our ability to require more complex measures and stratification over time. While section 1945A(g)(2)(A) of the Act, which applies to the section 1945A Health Home Core Set, requires any State reporting under that provision to be ''in such form and manner determined by the Secretary to be reasonable and minimally burdensome,'' this requirement applies to CMS regardless of whether it is repeated in CMS' regulations. We believe that we can and will meet this requirement by taking multiple steps and intend to keep doing so for all Core Sets. For example, as specified in § 437.10(a) and (e) of the proposed rule, States and providers of health home services under sections 1945 and 1945A of the Act are among the interested parties that are consulted in development of the Core Sets, and this process is designed to consider burden of reporting in measure selection. We have already released the list of measures included in the 2024 Child, Adult, and section 1945 Health Home Core Sets.[27] Additionally, we have released the list of measures under consideration for the 2024 section 1945A Health Home Core Set to allow States and health home programs time to prepare.[28] We also aim to align measures across programs as much as possible, and to identify measures for additional reporting that States already have the infrastructure to calculate. For example, the section 1945A Health Home Core Set under consideration currently contains 7 quality measures, all of which can be calculated using administrative claims data only.

Comment: One commenter recommended that CMS harmonize the Core Sets so that reporting is not duplicated across different programs, such that State reporting of the Child Core Set would mean that reporting would not be required again for the subset of children included in the health home. This commenter recommended that, for those children, only the additional health home-specific measures should need to be reported.

Response: While we aim to align measures across programs as much as possible, the Child, Adult, and Health Home Core Sets data are reported at different levels. Specifically, the Child and Adult Core Sets data is reported to us at the State level, and Health Home Core Sets data is reported to us at the program level. For this reason, the same calculation cannot be used in both the Child Core Set or Adult Core Set and either of the Health Home Core Sets, as States have not submitted the data in their Child and Adult Core Sets reporting that would be necessary for us to derive health home program rates from State-level reporting. Regarding duplication of reporting, section 1945A(g)(1)(B) of the Act requires section 1945A health home providers to report to the State information on all applicable measures for determining the quality of health home services provided by that health home provider, including to the extent applicable, child health quality measures and measures for centers of excellence for children with complex needs developed under section 1139A of the Act. Per section 1945A(g)(2)(A)(i) of the Act, the State then reports this information to us.

Comment: One commenter recommended that CMS remove measures which do not have National Quality Forum (NQF) endorsement from the Core Sets.

Response: We appreciate the submission of this comment, and it will be considered in the subregulatory measure identification process. However, we note that statute (sections 1139A and 1139B of the Act) does not limit the Child and Adult Core Sets to measures with NQF endorsement and, as required under the statute (sections 1139A and 1139B of the Act) for Child and Adult Core Sets, measures are selected through the Annual Core Set Workgroup process established by CMS. Health Home Core Sets are also selected through the Annual Core Set Workgroup process established by CMS, even though this process is not statutorily required for these core sets.

Comment: Several commenters recommended that CMS review the list of individuals who participate in the Annual Core Set Workgroup to ensure meaningful representation from beneficiaries of all ages and their advocates, including people with disabilities and behavioral health disorders (including substance use disorders). Several commenters requested that the Workgroup have representation of specific types of organizations and individuals, including but not limited to: beneficiaries, MCOs, purchasers of health care, providers and consumers and/or national organizations that represent adults, FQHCs, pharmacies and pharmacists, providers and health care professionals, and beneficiaries served through a Health Home (this would apply only to the Health Home Core Sets).

Response: We appreciate the submission of these comments and will take them into consideration as we organize future Workgroups. All

[26] *https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf.*

[27] CMS released both the 2023 and 2024 Child and Adult Core Sets in November 2022 (*https://www.medicaid.gov/federal-policy-guidance/downloads/cib111522.pdf*) and the 2023 and 2024 Health Home Core Sets in December 2022 (*https://www.medicaid.gov/medicaid/quality-of-care/downloads/2023-health-home-core-set.pdf*).

[28] Proposed 1945A Health Home Core Set *https://www.medicaid.gov/medicaid/quality-of-care/downloads/2024-1945a-health-home-core-set.pdf.*

Workgroup meetings are open to the public, and public comment is invited during each meeting.

Comment: One commenter recommended that CMS monitor the Workgroup process to determine if interested parties' feedback is being adequately addressed or if a formal rulemaking process is necessary.

Response: We appreciate the submission of this comment and will take it into consideration as we organize future Workgroups and monitor the public comment process.

Comment: One commenter recommended that CMS offer States and health care organizations financial assistance to develop and deploy health equity efforts, including funding support in addressing the capture of self-reported data. Another commenter recommended that CMS require States to submit plans for mitigating persistent disparities and regularly report on their progress to close access and quality gaps.

Response: While we appreciate these comments, they are outside the scope of this rulemaking, which addresses only Core Sets data and measurement. However, we note that Medicaid and CHIP Federal matching funds are available for State expenditures on the design, development, and installation (including of enhancements), and for operation, of mechanized claims processing and information retrieval systems. This could include State expenditures related to operating such systems for Core Sets reporting. We also note that under section 1903(a)(7) of the Act, Federal matching funds are available for activities necessary for the proper and efficient administration of the Medicaid State plan. This may include improving data reporting, which could promote greater health equity.

Comment: One commenter recommended that CMS examine and prioritize the selection of Child Core Set measures that can provide actionable data at the level of providers to continue to improve pediatric outcomes and focus on health disparities and measures that can provide the most value in terms of informing the quality of pediatric care.

Response: While we appreciate this comment, provider-level data is outside the scope of the rulemaking, which addresses reporting at the State and health home program level. We note also that the statutory mission of the Child Core Set, as stated in section 1139A(3)(D) of the Act, specifies ''the types of measures that, taken together, can be used to estimate the overall national quality of health care for children, including children with special needs, and to perform comparative analyses of pediatric health care quality and racial, ethnic, and socioeconomic disparities in child health and health care for children.''

Comment: One commenter recommended that CMS improve the measure sets' relevance to children with special health care needs and children with medically complex conditions included in sections 1945 and 1945A health home programs.

Response: We agree with the importance of reflecting all populations that are served in both section 1945 and 1945A health home programs in the Health Home Core Sets. The specific measures to be included in the Health Home Core Sets, which are determined through the workgroup process finalized in § 437.10(a), will be released through annual subregulatory guidance.

1. Annual Reporting Guidance

As discussed in section II.C.1. of the proposed rule, we proposed in §§ 437.10 and 437.15 to require that States use standardized formats and procedures established by the Secretary when reporting on the Child, Adult, and Health Home Core Sets. We also proposed in § 437.10(a)(3) and (b) that we would develop and annually update the reporting guidance needed by States to report on all applicable Core Sets and described the components of the annual reporting guidance. For a complete discussion of the components of the annual reporting guidance, please refer to the proposed rule section II.C.1.

In general, commenters supported the proposed annual reporting process, but requested clarification on what would be included in the reporting guidance. We are finalizing these provisions with revisions to §§ 437.10(b) and 437.15(a), where we have provided additional detail on reporting requirements. We discuss these revisions in sections II.D.2. and II.D.3. of this final rule. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Commenters noted that there are many details related to the contents of reporting guidance that were not addressed by the regulatory text. In particular, they asked for additional guidance as to: (1) whether CMS would continue to arrange licensing agreements with measure stewards related to the use and reporting of Core Set measures; (2) how CMS would identify the mandatory measures, populations to be included in mandatory reporting, and the process for reporting; (3) the timeline for reporting new measures; and (4) attribution rules for beneficiaries enrolled in different coverage during the reporting period and how to operationalize them.

Response: To address concerns raised by these commenters, through revisions to §§ 437.10 and 437.15, we have provided additional detail on reporting requirements and populations to be included in mandatory reporting, and we discuss these revisions in sections II.D.2. and II.D.3. of this final rule. We currently provide annual reporting guidance to States to support voluntary reporting, and as explained in this rule, this guidance will, in the future, include the requirements associated with mandatory reporting and will continue to be updated annually.[29] As specified in § 437.10(b), we will continue to provide detailed reporting guidance annually to States, which will include all of the information and technical specifications required for reporting of each of the Core Set measures, including the mandatory measures, populations to be included in mandatory reporting, the process for reporting, the timeline for requiring reporting new measures, and attribution rules and how to operationalize them. We will continue to execute licensure agreements with measure stewards as needed for States to report Core Set measures to CMS.

Comment: Multiple commenters recommended that, as future modifications or additions are made to the Core Set, CMS issue reporting guidance as soon as possible to give States, MCOs, and health care providers time to prepare for reporting. Some commenters recommended that CMS release reporting guidance in alignment with the NCQA reporting guidance release, while others recommended that CMS set a deadline for publishing reporting guidance by January 1st annually.

Response: We will take this feedback into consideration when developing Core Set reporting guidance and materials for public reporting. Measure stewards release updated guidance throughout the calendar year. Due to the need to adapt the reporting guidance developed by individual measure stewards, such as NCQA, for State-level reporting, simultaneous release of these materials with the measure steward is not feasible. We recognize the time and effort it takes States to prepare for Core Set reporting and expect to make every effort to publish reporting guidance as

[29] Reporting guidance will be posted here: *https://www.medicaid.gov/medicaid/quality-of-care/quality-of-care-performance-measurement/index.html.*

soon as possible following the release of the updated Core Sets.

Comment: Multiple commenters recommended that CMS consult MCOs and/or behavioral health organizations (BHOs) as CMS develops annual reporting guidance for States in order to promote awareness of these resources, as many States rely on MCOs to provide data for reporting on the Core Sets and will need to update their reporting systems to implement standardized reporting. Another commenter recommended that CMS clarify the role of MCOs in supporting providers and State agencies in their efforts to improve Medicaid and CHIP quality measurement.

Response: As part of our annual process to update reporting guidance, we review all of the technical assistance requests received related to specific measures, which often include questions submitted by MCOs/BHOs that are working on behalf of States to calculate Core Sets measures. The publication of reporting guidance and any updates regarding the Core Sets, including the publication of Core Set data products, is disseminated through a public listserv.[30] We defer to each individual State's Medicaid and CHIP agencies to determine the role MCOs and BHOs will have in in their State's Core Sets reporting and efforts to improve quality measurement within their State.

Comment: One commenter agreed with reporting data for partial-year enrollees at the State level, but recommended against attributing these data to specific MCOs if CMS stratifies reporting by health plan, noting that MCOs would have limited opportunity to work with members to accomplish necessary screenings and visits.

Response: Decisions regarding the continuous enrollment period and allowable gaps are established by the measure stewards for each measure. Core Set reporting applies to all beneficiaries who meet enrollment criteria in State Medicaid and/or CHIP programs. We will take this comment regarding health plan attribution into consideration as we develop reporting guidance regarding attribution and stratification categories.

2. Advancing Health Equity Through Data Stratification

Measuring and reporting on health disparities is a cornerstone of CMS' approach to advancing health equity. As discussed in section II.C.2. of the proposed rule, we proposed in § 437.10(d) requirements for stratification of Child, Adult, and Health Home Core Set data to enable us to monitor health outcomes for disparities between groups of individuals who may have different determinants of health. This approach to data reporting and stratification is aligned with Executive Order 13985, which calls for advancing equity for underserved populations.[31] We proposed that the annual reporting guidance identify the specific measures in the Child Core Set, the behavioral health measures on the Adult Core Set, and the Health Home Core Sets that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary. We note that in collecting and reporting data in accordance with the requirements of this rule, States and providers would be expected to comply with all applicable Federal non-discrimination laws. We also note that data stratification is intended to promote health equity for all patients and is not intended to promote discrimination or to create a conflict between a CMS requirement and a State's civil rights laws. Please refer to the proposed rule, section II.C.2., for specific discussions of the method for identifying measures for stratification, stratification factors, data suppression policies, and proposed timeline for phased-in stratification.

We believe that this stratification of data in the Child Core Set, Adult Core Set, and Health Home Core Sets measures is consistent with our statutory authorities. Regarding the Child Core Set, section 1139A(b)(2)(B) of the Act specifies that measures under the pediatric quality measures program shall be ''designed to identify and eliminate racial and ethnic disparities in child health and the provision of health care.'' In addition, section 1139A(a)(3)(D) of the Act required that the initial Child Core Set contain the ''types of measures that, taken together, can be used to estimate the overall national quality of health care for children, including children with special needs, and to perform comparative analyses of pediatric health care quality and racial, ethnic, and socioeconomic disparities in child health and health care for children.'' Regarding the Adult Core Set, section 1139B(a) of the Act requires the Secretary to utilize similar parameters for establishing the Adult Core Set. Additionally, section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, authorizes us to require stratification of the data that States report to us. Regarding the Health Home Core Sets, in addition to the authority provided by section 1902(a)(6) of the Act, section 1945(g) of the Act requires section 1945 health home services providers to report to the State, in accordance with such requirements as the Secretary shall specify, on all applicable measures for determining the quality of such services. Section 1945A(g)(2)(A)(i) of the Act requires States implementing the section 1945A health home benefit to submit to the Secretary, in such form and manner determined by the Secretary to be ''reasonable and minimally burdensome,'' all section 1945A quality reporting data that was submitted to them under section 1945A(g)(1) of the Act. The information providers report to the State under section 1945A(g)(1)(B) of the Act includes, to the extent applicable, child health quality measures developed under section 1139A of the Act.

We received public comments on the proposed approach to stratification of Core Set data, and in general, commenters supported the proposed process. We are finalizing these provisions generally as proposed in § 437.10(b)(7) and (d), with minor wording changes. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported the proposed requirement to phase in stratified reporting over a period of 5 years and recommended that the Secretary specify which measures must be stratified in order to promote consistency and comparability across States rather than allowing States to decide the measures and factors for which they will submit stratified data each year. A few commenters recommended instead that States be able to choose based on data availability or State health care priorities. Multiple commenters also supported the proposed requirements that States stratify certain measures by demographics, health care delivery systems, and other characteristics to enable better care comparisons and identification of health disparities. Some commenters recommended that CMS ensure that stratified data be reported for both managed care and FFS delivery systems. Several commenters supported the improved and expanded

[30] To join the Core Set listserv email: *MACQualityTA@cms.hhs.gov.*

[31] Executive Order 13985: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

collection of data, and analysis of quality measures by population (such as dually eligible individuals), stratification categories (such as race and ethnicity or disability status), and delivery systems and provider types. They noted that these activities would allow for the deployment of strategies that better account for the needs of beneficiaries and further understanding of barriers to care and health disparities. One commenter also recommended that CMS make available reporting guidance, information on potential or expected data sources, and share examples of State data collection, organization, and lessons learned.

Response: We worked to find a balance in the reporting of State data that meets the statutory reporting requirements under sections 1139A(c)(2) and 1139B(d)(2) of the Act while taking into consideration data quality and the ability to conduct comparative analysis, and we determined that allowing States to choose which measures to stratify based on data availability or State health care priorities would limit our ability to publish standardized core measure data that could be compared across States and over time. Therefore, in the methodology we are finalizing in § 437.10(b)(7) and (d), stratified reporting will be phased in over a period of 5 years, and the Secretary will specify which measures should be stratified and by which factors data will be stratified. We will provide technical assistance to support mandatory reporting of stratified data and will ensure that States have access to reporting guidance and other tools in order to assist with annual reporting.[32]

Comment: One commenter stated that the Core Sets were initially developed as a within-State quality improvement tool. Because State Medicaid programs vary greatly in eligibility and offerings, it is important that proposed stratifications do not lead to State-to-State comparison without consideration for the populations served. The commenter also stated that stratifications would add to State reporting burden while not adding additional value or information for improvement, and recommended stratification be piloted first to determine if it is needed.

Response: The Child Core Set was intended not only to provide States with a tool to drive improvement for their enrollees but also to provide an estimate of the overall national quality of health care for children (section 1139A(a)(5) of the Act). As discussed previously in this final rule, we believe that stratification of data in the Child Core Set, Adult Core Set, and Health Home Core Sets measures is consistent with our statutory authorities. Stratified Core Set quality measure data will enable CMS and States to identify the health outcomes of underserved populations as well as potential differences in health outcomes between populations. Stratified data can also inform adoption of broadly applicable quality improvement initiatives that address the drivers of health disparities experienced by underserved populations. Due to the variability across States in the populations served by Medicaid and CHIP, and the different populations and health care services included in each core measure, a pilot project using a subset of States and/or measures would not provide sufficient data or results that could be generalized to provide an understanding of differences in health outcomes overall.

Comment: Several commenters submitted recommendations and requests related to the details of stratified reporting, such as definitions of specific categories, data suppression policies and how to handle missing data, and different measures of delivery systems.

Response: We will take these comments into consideration when developing annual reporting guidance. We are finalizing the list of stratification factors in § 437.10(b)(7) with minor edits, to include race, ethnicity, sex, age, rural/urban status, disability, and language, as well as additional factors as may be specified by the Secretary and informed by annual consultation with States and interested parties.

Comment: Several commenters recommended that consistent data standards for stratification of race, ethnicity, and language, across programs and agencies would clarify and facilitate data collection. However, one commenter noted that new standards should not inhibit the ability of States to tailor their data fields to reflect their populations as long as they are able to be aggregated to Federal categories and that any guidance provided by CMS in this area should also recognize the experiences of people with multiple racial and/or ethnic identities. Additionally, several commenters suggested that CMS include a ''Middle Eastern or North African'' response among the race and ethnicity measures, allowing for stratified health outcomes for a population that experiences disparities.

Response: The specific response categories included in stratified reporting will be addressed as part of the reporting guidance process that is discussed in the rule. We will take these recommendations into consideration when developing annual reporting guidance, considering data availability, data quality, and burden to States. We expect to align with Department of Health and Human Services (HHS) data standards for stratification, based on the disaggregation of the 1997 Office of Management and Budget (OMB) Statistical Policy Directive No 15.[33] We expect to update Core Set reporting stratification categories if there are any changes to OMB or HHS Data Standards.

Comment: One commenter recommended that unknown, missing, or nonresponses on demographic variables be its own stratification category with its own associated measure rate. Another commenter recommended that CMS provide technical assistance to States on how to collect and report race and ethnicity information, including how States should handle large percentages of data records with ''unknown'' race and ethnicity. Several commenters recommended that an optional category for ''declined to answer'' or similar category be included in State reporting. A few commenters recommended a methodology for identifying beneficiaries with a disability based on disability questions from the American Community Survey. Another commenter noted that there is not a Federal standard defining ''disability'' and requested that CMS establish one for consistency in reporting in this and other programs.

Response: We will take this feedback into consideration when developing Core Set reporting guidance on stratification requirements. This area of data collection and reporting is evolving rapidly, and we expect to provide additional technical assistance and support in this space in the future.

Comment: Several commenters supported all the proposed requirements for stratification but recommended either faster or slower implementation. Some commenters suggested that States be required to report stratified data by the 2024 reporting period rather than phase in this requirement. Another commenter noted that a shorter phase-in period would not be overly burdensome to States given the enhanced Federal

[32] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

[33] The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=53.*

Medicaid match for upgrading computer systems for this kind of reporting. Multiple commenters provided alternate phase-in schedules for stratification of Core Set measures.

Response: We agree on the importance of reporting stratified data to help identify and eliminate health disparities across populations. Reporting of stratified data is a cornerstone of our approach to advancing health equity, as outlined in the proposed rule. We determined that a shorter phase-in period, such as between 1 and 4 years, would not likely be operationally feasible because of the potential systems and contracting changes (to existing contracts or the establishment of new contracts) that States may be required to make in order to collect these data. For example, additional reporting requirements may need to be added to State contracts, changes may be needed to data sharing agreements with MCOs, and modifications of databases or systems might be required to record new variables. Based on discussions with States regarding the feasibility of reporting stratified data, and the comments received supporting the proposed timeframe, we have addressed the comments recommending a longer duration of phase-in by revising § 437.10(b)(5) to include flexibility in the reporting of some populations in the initial years of reporting the Child and Adult Core Sets. Of note, the section 1945A health home benefit requires providers of that benefit to report to States on quality measures as a condition of payment. The populations which will be optional for States to include in reporting of the Child and Adult Core Sets will be specified in annual subregulatory guidance. In addition, we anticipate that States will not need more than 5 years to implement systems and contracting changes, or any additional support needed to report stratified data. We plan to work collaboratively with States to provide the technical assistance and reporting guidance necessary to support reporting of stratified data.[34] While States may be eligible for an increased Federal match for systems changes, States still bear a share of the cost, and making the needed systems changes is time-intensive, likely requiring several years or more to implement. We have therefore determined that the proposed 5-year phased-in approach to data stratification is reasonable and would also be consistent with section 1945A(g)(2)(A) of the Act for 1945A health home programs. With this approach, we are balancing our strong interest in identifying differences in health outcomes between populations (as supported by our statutory authorities, as discussed previously in this final rule) with the operational challenges that States may face in implementing these requirements. We are finalizing the proposed phase-in time frames under § 437.10(b)(7) and (d) as proposed. States will thus be required to submit stratified data for 25 percent of the measures on each of the Core Sets (the Child Core Set, behavioral health measures within the Adult Core Set, and Health Home Core Sets) for which the Secretary has specified that reporting should be stratified by the second year of annual reporting after the effective date of the final rule; 50 percent of such measures for the third and fourth years of annual reporting after the effective date of the final rule; and 100 percent of measures beginning in the fifth year of annual reporting after the effective date of the final rule, on all factors as specified by the Secretary pursuant to § 437.10(b)(7), such as race and ethnicity, sex, age, rural/urban, disability and language.

Comment: One commenter recommended that CMS modify the stratification schedule to consider a phased-in approach based on the stratification factor, for example, race, instead of the number of measures.

Response: We appreciate this feedback and will consider it when developing annual reporting guidance. Specific factors by which data will by stratified will be delineated in annual reporting guidance, and we will select these factors based on relevance and feasibility with the plan to add over time as the quality and completeness of data improve. We are finalizing § 437.10(d) generally as proposed.

Comment: Multiple commenters recommended strategies for determining which measures should be stratified first and by which stratification factor(s) (that is, separate factors or multiple factors simultaneously). These strategies included working collaboratively with States and State-contracted entities, aligning with the measures and timeline for stratification as determined by NCQA Healthcare Effectiveness Data and Information Set (HEDIS) for their measures, beginning the phase-in with measures that are currently stratified for NCQA HEDIS reporting, and giving States the flexibility to decide the measures and factors for which they will submit stratified data each year. Several commenters recommended that CMS prioritize how measure stratification is phased in based on the topics of most urgent need, such as maternal and behavioral health, or measures addressing disease prevention. Some commenters encouraged stratification of the Core Set measures based on data obtained from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, while others encouraged CMS not to require stratified CAHPS data. Some commenters encouraged CMS to ensure buy-in from interested parties such as States, beneficiary groups, and providers on measures selected for stratification so that States have adequate time to ensure that they are reporting high quality data.

Response: We will take these ideas into consideration when developing annual reporting guidance, and plan to work collaboratively with States to provide the technical assistance and reporting guidance necessary to support reporting of stratified data.[35] We are finalizing as proposed the phase-in process for reporting stratified Core Set measures in § 437.10(b)(7) and (d) of this final rule.

Comment: We received many comments making recommendations on stratification factors for State reporting of Core Sets in § 437.10(b)(7) and (d) such as:

- Addition of sexual orientation and gender identity; socio-demographic data; pregnancy status; and socioeconomic status;
- Addition of the State's Medicaid expansion status with respect to coverage of adults under age 65 who are described in 42 CFR 435.119, as well as extended coverage during the 12-month postpartum period under section 1902(e)(16) and 2107(e)(1)(J) of the Act; and
- Recommendations both for and against addition of health care delivery system as a stratification factor. Many commenters noted that stratification by health plan could identify trends in quality, advance State alternative payment methodologies, and support oversight. One commenter noted that stratification by health plan would be especially helpful in comparing plans that are engaged in quality improvement projects to those that are not. Other commenters suggested that it may be helpful for certain measures to be stratified on a multi-level basis, for example, health plan data disaggregated by race, ethnicity, and other factors. Another commenter suggested that stratification by delivery system be used

[34] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

[35] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

for quality improvement efforts only, and public reporting occur at the State level. A few commenters recommended that CMS not require stratification by health plan given the regional and population differences served by Medicaid managed care in States unless CMS can account for variation in geography, population, and benefits.

Response: We will take these comments into consideration when developing annual reporting guidance, which will include stratification factors. We are finalizing § 437.10(b)(7) and (d) generally as proposed to allow for the additional stratification by other factors as may be specified by the Secretary and informed by annual consultation with States and interested parties per § 437.10(a)(3), which could include stratification by health plan or other factors described previously in this final rule. This approach provides us with flexibility to adjust stratification requirements by factors that are both feasible and relevant in a rapidly evolving field.

Comment: Many commenters discussed both the positives and negatives of CMS potentially using geolocation or other types of data to impute identification of race and ethnicity. Several commenters recommended that CMS not use imputed data to calculate race and ethnicity data, and instead focus efforts on improving the collection and completeness of self-reported race and ethnicity data, and minimizing the burden of data collection and reporting, particularly on consumers. Multiple commenters recommended that CMS use imputed data sparingly, with some suggesting that CMS share any imputed data with States for review prior to publication, or not publicly report the results of stratification based on imputed data given the lack of validity of such data. Commenters noted it is critical that CMS provide details on what specific imputation methods would be used to stratify the Medicaid data, as many methods have been developed based on Medicare data and may not yield as accurate results in the Medicaid population. Additionally, one commenter recommended use of standardized imputation methods across the industry.

Response: We agree that self-reported beneficiary data should be used whenever possible, and that it is important to undertake efforts to improve data quality. To that end, in our efforts to improve the quality of race and ethnicity data, we have: issued guidance on reporting race and ethnicity in Transformed Medicaid Statistical Information System (T–MSIS); [36] provided State technical assistance on identifying and investigating data quality issues based on unspecified, unknown, missing or invalid race and ethnicity data and worked with States to improve data quality and completeness; and published data quality assessments in the Medicaid Data Quality (DQ) Atlas. Complete demographic information from beneficiaries is the optimal source of data for stratification, and our development of imputation models is intended to complement this source with a reliable method to identify disparities in the face of missing or inaccurate data.[37] We will release detailed documentation about the methodology used to develop imputations prior to the release of these data. We will take these suggestions into consideration and will consult with States on the use of imputed race and ethnicity when developing annual reporting guidance, technical assistance, and other resources for States.

Comment: We received several comments about other sources of demographic data. Several commenters recommended that CMS use demographic data collected on the Medicaid and CHIP eligibility application and provide guidance that covers the entire process of data collection, reporting, and sharing. In reference to self-reported data, one commenter suggested CMS ensure that consumers are aware of the reasons why the data are being collected, that the process is voluntary, that no adverse action will result for failing to provide the data (that is, no loss of health benefits or access to services), and of how the data may be used, shared, and disclosed. Multiple commenters recommended that the CMS Single, Streamlined Online Application be revised to allow beneficiaries to select a ''decline to answer'' option in response to demographic questions. Other commenters suggested using State administrative data to supplement missing demographic information, and the use of electronic data in general, and recommended that CMS provide technical assistance on how to report measures for individuals with ''unknown'' race/ethnicity. One commenter suggested providing detailed measure information, such as indicating the data source or imputation methodology for demographic and performance data.

Response: Modifications to the Single Streamlined Application and State eligibility forms are outside the scope of this rulemaking; however, we will take the suggestions into consideration when making updates to the Single Streamlined Application. The Single Streamlined Application follows the OMB data standards for collection of race and ethnicity data, and use of this application is optional for States.[38] When developing their own applications, States are encouraged to use the same standards and must ensure that questions asking about race and ethnicity are optional. The Single Streamlined Application eligibility application available through HealthCare.gov includes the following language alongside questions about race and ethnicity: ''Selecting this person's race and ethnicity helps the U.S. Department of Health and Human Services improve service to all people using the Marketplace. We use this information to make sure everyone gets fair access to coverage. Providing this information won't impact eligibility, plan options, or costs.'' [39] State Medicaid and CHIP agencies have the flexibility to choose to include similar language in their eligibility applications and are better positioned than CMS to collect this data directly.[40]

Comment: Several commenters recommended that CMS acknowledge that States with smaller and/or more homogeneous populations may not be able to report data for a sufficient number of individuals for some stratification categories, such that CMS will need to suppress data to ensure privacy protections.

Response: We agree with the need to protect beneficiary privacy. We noted in the proposed rule that we will follow data suppression policies for measure stewards in addition to the CMS Cell Size Suppression Policy such that if sample sizes are too small, data will not be publicly reported to avoid a potential violation of privacy. We are finalizing § 437.10(d) generally as proposed.[41] We plan to provide technical assistance to

[36] *https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/109701.*

[37] Elliott, Marc N., et al. ''Using the Census Bureau's surname list to improve estimates of race/ethnicity and associated disparities.'' Health Services and Outcomes Research Methodology 9.2 (2009): 69–83.

[38] The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=53.*

[39] Health Insurance Marketplace Application Instructions: *https://www.healthcare.gov/downloads/marketplace-application-for-family-instructions.pdf.*

[40] States could adopt this or similar language in their application, regardless of the modality (paper, online, phone).

[41] CMS Cell Suppression Policy: *https://www.hhs.gov/guidance/document/cms-cell-suppression-policy.*

States as needed and will publish data suppression guidance in annual reporting guidance.

Comment: One commenter recommended establishing minimum denominators to identify statistically significant changes in disparities.

Response: We will take this comment into consideration for future guidance regarding health disparity analysis.

Comment: Some commenters suggested methods for CMS to align with other measure sets and organizations. Several commenters requested that CMS align with NCQA HEDIS as much as possible, including stratification categories and age ranges, and that other stratification factors be phased in after race and ethnicity. One commenter recommended that CMS explore using data submitted to NCQA for accreditation to ease burden on providers, plans, and States. Another commenter recommended that CMS encourage States to use the NCQA Electronic Clinical Data System (ECDS) reporting method for applicable measures. One commenter suggested the Federal government streamline efforts and standardize measures sets across all payers, and that CMS, Health Resources and Services Administration (HRSA), and HHS provide available data when possible to reduce burden to States and providers. Another commenter suggested CMS explore opportunities to get a broader view of child health by connecting different Federal databases, including those that collect data for Title V, public health, child welfare and children's mental health programs, and encourage these same connections at the State level.

Response: We will take these ideas into consideration when developing annual reporting guidance. We agree with the commenters on the importance of parsimony, alignment, and harmonization in quality measurement to the extent possible. Throughout the annual Core Set review process, we actively engage with a variety of internal and external interested parties, Federal partners, other reporting agencies related to Medicaid and CHIP, and Medicare and Marketplace. This process facilitates measure alignment as appropriate, noting areas of needed divergence due to differences in reporting levels.

Comment: Several commenters recommended that CMS work with other Federal agencies on Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (API) standards, stating that aligning with FHIR standards would resolve many of the challenges in accessing both administrative and clinical data required to report Core Set measures, including demographic data required for stratification. These commenters encouraged CMS to explore ways to leverage the current interoperability and information sharing regulations to promote data sharing across systems and minimize the reporting burden on consumers. One commenter recommended that CMS undertake an assessment of the barriers and opportunities to enable data exchange and information systems interoperability in order to help report outcomes-based measures. Another commenter noted that simply relying on Electronic Health Record (EHR) vendors to implement FHIR and United States Core Data for Interoperability (USCDI) standards will not be enough to ensure complete and accurate data. One commenter noted challenges with sharing data across systems with different EHRs. Several commenters expressed concern about data entry errors creating an increased State burden and recommended that CMS consider technical interventions such as open-source tools or use of structured electronic data files, standardized spreadsheets, API or other upload options to reduce burden and errors created through manual data entry.

Response: We will take these comments into consideration when developing annual reporting guidance, technical assistance, and other resources for States.

D. Annual Reporting on the Child, Adult, and Health Home Core Sets

As discussed in section II.D. of the proposed rule, we proposed in §§ 437.10 and 437.15 the key requirements and procedures for States in reporting both mandatory and voluntary measures, including the procedures to identify measures that States would report, measures that we would report on behalf of States, and measures for which States may elect to have us report on their behalf. We also solicited comments on what technical assistance we should provide to support these activities.

We received public comments on the process proposed in §§ 437.10 and 437.15, and in general, commenters supported the proposed process. We are finalizing these provisions with revisions to §§ 437.10 and 437.15. We describe in section II.D.2. of this final rule our revisions to §§ 437.10 and 437.15 regarding reporting of mandatory measures, in addition to a revision regarding survey-based measures in § 437.10(b)(1)(v). We describe in section II.D.3. of this final rule our revisions to §§ 437.10 and 437.15 regarding populations required for mandatory reporting. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters recommended that CMS allow States the option to self-report; or allow other alternate data sources such as Transformed Medicaid Statistical Information System (T–MSIS) Analytic Files (TAF) to be used to calculate measures on States' behalf. However, these and other commenters requested additional information on the use of T–MSIS/TAF and noted that alternate data sources should be used only under certain conditions, namely: that States are allowed to opt-out; that States are provided the opportunity to review and confirm results; and that the calculation methodology adheres to the measure specifications including use of denied claims, among other stipulations. One commenter also requested that CMS provide States with assistance in investigating data discrepancies or measurements that seem to be in error.

Response: We will continue to assess whether T–MSIS/TAF or other alternate data sources can be used to calculate Core Set measures on behalf of States. As stated in § 437.10(b)(1)(iv), we will continue to calculate selected measures on States' behalf using alternative data sources and, in these cases, we anticipate providing States with an opportunity to preview data. For other selected measures, as stated in § 437.10(b)(1)(iv), we will allow States the option to either self-report (if they adhere to CMS-issued reporting guidance as per § 437.15(a)(3)), or allow the measures to be calculated on States' behalf using alternate data sources. We currently provide States an opportunity to preview data for any measure calculated utilizing alternate data sources such as ''Live Births Weighing Less Than 2,500 Grams'' on the Child Core Set and ''National Core Indicators Survey'' on the Adult Core Set and intend to continue doing so. We are finalizing §§ 437.10(b)(1)(iv) as proposed and § 437.15(a)(3) with a minor wording change.

Comment: Several commenters raised concerns with the use of T–MSIS/TAF data to calculate Core Set data or for stratification, as there may be issues with the data validity for many States, and recommended that CMS not use T–MSIS for reporting on behalf of States. For example, some measures may require more years of data than are available through T–MSIS, or data reported through T–MSIS may be incomplete.

Response: We assess each Core Set measure individually to determine if it is able to be calculated using T–MSIS/

TAF data, based on the technical specifications, considering the years of data available in T–MSIS and also the types of data required to accurately calculate that measure. As stated previously in this final rule preamble, we also intend to allow States to preview all Core Set data generated by T–MSIS.

Comment: One commenter recommended that CMS develop a third-party validation process that certifies State measure logic and audits Information Technology (IT)/measurement systems in a standardized way. This commenter also suggested validating supplemental data from the source, providing the example of NCQA's Data Aggregatory Validation program. Another commenter recommended that CMS test and validate stratified results to ensure they are accurate.

Response: We agree with the commenter on the importance of data quality in Core Set reporting. We have built a pre-publication quality assurance process into the review of all Core Sets data. Through this process, we work with States to resolve data quality issues and confirm any deviations from the reporting guidance. Sections 1139A and 1139B of the Act require the Secretary to collect, analyze, and make publicly available the information reported by States; however, these sections do not require the levels of data validation recommended by these commenters. While sections 1945(g) and 1945A(g) of the Act give the Secretary the authority to establish requirements related to the form and manner of health home quality reporting, they do not specify that the Secretary must require data validation of submissions. We will continue to evaluate data validation needs in developing resources for Core Set reporting.

Comment: One commenter recommended that CMS maximize the use of performance data that can be collected and transmitted electronically, and to minimize manual data collection. We understand the commenter to be recommending that the measures on the Core Sets primarily be those that can be calculated using only administrative or EHR data versus those that require manual chart reviews or in-person surveys.

Response: We appreciate the submission of these comments and will take this feedback into consideration in the subregulatory measure review process.

Comment: One commenter noted that if Health Homes are required to report to the State, each Health Home will require extensive technical assistance, funding for technical assistance and result validation, expertise in quality measure specifications, and staff. Some commenters noted that Health Home programs and their providers of Care Management do not have reliable, current, and consistent access to claims, encounter, and clinical data to effectively report on these measures. They further stated that Health Home care management is not itself a clinical protocol model of care management, but rather a set of care management practices that facilitate clinical care, address social care needs, provide education, increase member health literacy, and address health equity and disparities to improve health outcomes, all of which makes it challenging to report on the Health Home Core Sets.

Response: This final rule implements statutory reporting requirements for providers of section 1945 and section 1945A health home services at sections 1945(g) and 1945A(g)(1)(B) of the Act. Providers of section 1945 health home services are required to meet the reporting requirements specified at section 1945(g) of the Act, and providers of section 1945A health home services are required to meet reporting requirements specified at section 1945A(g)(1)(B) of the Act. If a Health Home provider is submitting data into a State-based system that the State is then using to calculate and report the Health Home Core Sets measures to us, those data submissions from the provider to the State would satisfy the statutory requirements under sections 1945(g) and 1945A(g)(1)(B) of the Act. Comprehensive care management services are not a set protocol but rather one of the six services included in both the section 1945 and section 1945A Health Home benefits, as specified at sections 1945(h)(4)(B)(i) and 1945A(i)(4)(B)(i) of the Act. We have provided additional information about how we interpret this component of the section 1945 benefit in frequently asked questions (FAQs).[42] Health Home quality measure reporting has always been mandatory for participating providers under both sections 1945 and 1945A of the Act (even if using CMS' recommended measures has not been mandatory), and health home providers will need to coordinate with the State Medicaid Agency to seek assistance with Core Set reporting. We understood the comment to express the belief that the Health Home Core Set measures will be challenging to report, because the health home model does not provide direct, clinical care services to patients. This health home benefit is designed to be a care coordination model, and we recognize that implementing a service model that is separate from the provision of direct, clinical care services to patients may be a shift for some providers and States from models that provide direct, clinical care services, and that data sources may be different between the two types of models. We are available to provide technical assistance to States to navigate any challenges they may have when reporting Health Home Core Sets, and as such, we do not believe the reporting burden on States and providers is unreasonable.[43]

Comment: One commenter recommended allowing a minimum of 18 months to develop, test, and deploy new reporting requirements from a health IT standpoint once a State provides technical specifications to developers. Another commenter proposed that CMS consider that whenever multiple mandatory hybrid and survey measures are introduced in 1 year, staffing constraints, contractual agreements, procurement cycles, and similar issues may have an impact on States' abilities to gather data and calculate rates.

Response: We will take these comments into consideration when determining additions to the Core Sets for mandatory reporting.

Comment: One commenter requested that we explain whether the reporting requirements would increase the reporting burden on States and would *not* increase the burden on Indian Health Service (IHS) or Tribal facilities. They further recommended that if there was a reporting burden on IHS or Tribes and Tribal Organizations that CMS provide the same technical assistance to Tribes as it provides to States.

Response: We will provide States with technical assistance[44] related to Core Set reporting and will encourage States to work with Tribes and Tribal Organizations to improve data sharing. We recognize that States and Tribes establish individual contractual agreements that might affect the availability of Tribal data for Core Sets reporting. Given the different responsibilities for reporting that States and health care providers (such as those operated by IHS, Tribes, and Tribal Organizations) will have and the

[42] Health Home FAQs (January 21, 2016), *https://www.medicaid.gov/sites/default/files/2020-02/health-homes-section-2703-faq.pdf.*

[43] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

[44] About the Medicaid and CHIP Core Set Technical Assistance and Analytic Support Program: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

differences in resources available to them, it is hard to gauge for whom the burden of reporting will be greater or lesser. States should undertake Tribal Consultation related to reporting of Core Set measures, and are encouraged to coordinate with IHS, Tribes, and Tribal Organizations, to support data sharing.

Comment: One commenter noted a need for technical assistance incorporating States' Immunization Registry into their data warehouse, with tasks such as mapping individuals from the registry against Medicaid members and identifying the percent match rate. This commenter also stated that their State may need assistance with including CHIP enrollees' birth and mortality records from the State's Vital Statistics Office into their Medicaid and CHIP data warehouse.

Response: We will take this feedback into consideration when developing technical assistance resources and reporting guidance for Core Set reporting.

Comment: Multiple commenters recommended that CMS continue to offer technical assistance using a variety of formats including written guidance, standard templates, FAQs, measure specification and coding assistance, sharing of best practices, one-on-one State-specific technical assistance, learning collaboratives, direct communication with the technical assistance contractor, and instructional webinars that allow for questions. Commenters noted these have been effective mechanisms and will be needed in the future to meet mandatory reporting requirements. One commenter recommended templates and examples as part of technical assistance, while another recommended further clarification, structuring, and additional details in the reporting guidance to help streamline reporting and reduce error, but also to help States conduct quality assurance for their results. Additionally, several commenters requested technical assistance on data sharing with Federal and commercial partners, data stratification requirements, and how to address data limitations such as small sample sizes.

Response: We thank the commenters for their feedback on technical assistance methods and needs. We will provide technical assistance and will consider the suggestions when developing future technical assistance resources.

1. Adherence to Reporting Guidance

As discussed in section II.D.1. of the proposed rule, we proposed in § 437.15(a)(3) to require States to report on the Core Sets in a manner that adheres to CMS-issued reporting guidance described in § 437.10(b), which we proposed would include procedures and standardized formats for reporting measure data.

In general, commenters supported these proposals, and we are not making any changes to them in response to these comments. Below is a summary of the public comments we received regarding specific components of these proposals and our responses.

Comment: Multiple commenters concurred with CMS requiring States to adhere to the annual reporting guidelines to enable comparisons across States on quality performance and to calculate national performance rates for quality of care. Other commenters noted that standardized reporting should be the minimum requirement, and expectations for reporting should increase over time.

Response: We agree that requiring States to adhere to the reporting guidance, which we are finalizing in § 437.15(a)(3), is essential to provide effective comparisons across States on quality measure performance and to derive national performance rates for the care provided to Medicaid and CHIP beneficiaries. We also recognize that adherence to CMS-issued reporting guidance as described would be a substantial change from current reporting for some States. Recognizing the challenges that States may face in reporting stratified measure data and data for certain populations, we are finalizing in this rulemaking a phase-in approach for both the required stratification in § 437.10(d) and the reporting for certain populations in § 437.10(c), with stratified reporting of all mandatory measures required in the fifth year of annual reporting after the effective date of part 437 of this final rule.

Comment: Multiple commenters expressed concerns regarding strict adherence to reporting guidance as some deviations are the result of underlying differences in how State Medicaid programs or their data systems are structured. For example, some States limit the number of diagnosis codes that MCOs can submit, which may result in an eligible beneficiary being excluded from, for example, a diabetes measure if diabetes was not one of the highest diagnosis codes submitted for a visit in which multiple conditions were addressed. Another commenter requested that allowances be made for States to use the most reliable data source available, stating for example, the use of birth/vital records data vs. claims data for pregnancy/birth-related measures provides more specific information than can be found in claims data alone. One commenter proposed that if adherence is required, States should be permitted to explain any underlying systems differences that result in un-representative rates, and CMS should include this information with public reporting.

Response: Adherence to the reporting guidance is essential to provide effective comparisons across States on standardized quality measure performance and to derive national performance rates for the care provided to Medicaid and CHIP beneficiaries. As such, we are finalizing § 437.15(a)(3) to require that States adhere to reporting guidance issued by CMS. We will provide technical assistance to States to support their ability to do so.

Comment: Several commenters requested that reporting guidance address the level of data completeness required to ensure that the stratified rate would be considered valid. Another commenter recommended that technical assistance be focused first on improving data quality.

Response: We will take these ideas into consideration when developing technical assistance resources and reporting guidance for Core Set reporting.

Comment: Several commenters requested that CMS reporting guidance for the Core Sets be identical to the measure developers' specifications to allow organizations to report measures used in multiple programs consistently. Several commenters made this recommendation specifically due to the burden associated with reporting measures that deviate from NCQA HEDIS specifications, while others also recommended this approach specifically if deviation from CMS guidance is no longer permitted. One commenter also recommended that CMS continue allowing States to report using audited MCO NCQA HEDIS rates.

Response: We will consider these comments when developing reporting guidance. Core Set reporting is State-level or health home program-level reporting, while NCQA HEDIS is plan-level reporting, and therefore, measure adaptations are necessary for us to provide guidance to States for State- or Health Home program-level reporting. In making measure adaptations, we work closely with measure stewards, including NCQA, to develop reporting guidance and to make as few adaptations to the technical specifications as possible. Such adjustments generally are limited to adjusting the age ranges of a measure to align with either the Child or Adult Core Sets.

Comment: One commenter encouraged CMS to be mindful of implementation timelines, which may overlap with States' work related to the restoration of eligibility and enrollment operations, including terminations of enrollment, following the end of the continuous enrollment condition under section 6008(b)(3) of the Families First Coronavirus Response Act, as amended by the CAA, 2023, a process referred to as ''unwinding.''

Response: The timeline for mandatory reporting was statutorily established in 2018 to implement mandatory annual reporting of the Child Core Set and the behavioral health measures on the Adult Core Set, and these statutes do not include any provisions allowing us to modify the implementation timeline. We interpret the language in the Bipartisan Budget Act of 2018 and the SUPPORT Act to mandate annual reporting of these Core Sets beginning with the annual State report on FFY 2024 and align with State reporting of the 2024 Core Sets, currently projected to occur in Fall 2024. However, consistent with § 437.10(c) and (d), to minimize State burden, we plan to phase in requirements for measure stratification and Child and Adult Core Sets reporting for populations for which States do not have data access.

2. Reporting of Mandatory Measures

As discussed in section II.D.2. of the proposed rule, we proposed a methodology to phase in reporting of certain measures, including those that may be complex or difficult to report, those that are newly added to the Core Sets, or those that had significant updates to technical specifications from the prior year. We also asked for comment on how best to phase in reporting, the optimal frequency for reporting of outcome and survey-based measures, technical assistance States may need, and promising practices and approaches for data collection and data linkages.

We received comments stating that the Secretary does not have the statutory authority to delay the reporting of selected measures for any of the Core Sets, in addition to many comments supporting the proposed phased-in reporting process for mandatory measures. Upon additional review, we have determined that all of the measures currently on the Child Core Set and all of the behavioral health measures on the Adult Core Set should be subject to mandatory reporting in 2024. The majority of the measures proposed for the initial mandatory measure set for these Core Sets can be calculated using administrative data and have been on these Core Sets for many years, specifically, a median of 7 years for the Child Core Set and 10 years for the behavioral health measures on the Adult Core Set. Based on this analysis, and the fact that we have already released the list of measures included in the 2024 Child and Adult Core Sets,[45] allowing States significant time to prepare to report on these measures, we believe that all measures on the 2024 Child Core Set and all behavioral health measures on the 2024 Adult Core Set can be reported by States and, in this final rulemaking, are requiring that States report on all of them.

We have similarly determined that States and health home providers must report on all measures in the section 1945 and/or 1945A Health Home Core Sets, to better inform CMS evaluations of these health home programs and help us to analyze health home measures. Section 1945(g) of the Act specifies that, as a condition for receiving payment for section 1945 health home services, a health home provider shall report to the State, in accordance with such requirements as the Secretary shall specify, on all applicable measures for determining the quality of such services. Section 1945A(g)(1)(B) of the Act states that to receive payments for section 1945A health home services from the State a health home provider shall report to the State information on all applicable measures for determining the quality of health home services provided by such provider, including, to the extent applicable, child health quality measures and measures for centers of excellence for children with complex needs developed under title XIX, title XXI, and section 1139A of the Act. Additionally, section 1945A(g)(1)(C) of the Act requires section 1945A health home providers to report to the State such other information as the Secretary shall specify in guidance. In sum, both health home program statutes require health home providers to report to States on all applicable health home quality measures and give the Secretary discretion to identify the measures required for reporting each year. Since the inception of the section 1945 health home benefit, we have strongly encouraged States implementing that benefit to report on all applicable Health Home Core Set measures specified by the Secretary, and most have done so. Although prior to this rule, Health Home Core Set reporting has not been mandatory, we have no indication that States currently reporting the section 1945 Health Home Core Set measures have faced major burdens in doing so, and 100 percent of the current section 1945 Health Home Core Set measures can be reported using administrative claims only. When selecting measures to add to the Health Home Core Sets, we have been careful to ensure States and providers are able to report on all selected measures, and to ensure that the data provided when reporting on the measure would be useful for monitoring program performance and the quality of services provided to beneficiaries enrolled in the health home program. Based on the high rate of voluntary health home measure submission thus far, and the careful consideration we have given to measure selection, it is reasonable for CMS to expect States to comply with mandatory reporting for all measures on both of the Health Home Core Sets in the future. Additionally, since both sections 1945 and 1945A state that health home providers are statutorily required to report to the State as a condition of payment, States should have these data readily available for reporting to us. Finally, reporting of all measures on the Health Home Core Sets would inform CMS evaluation of both health home programs, assist us to identify racial, socioeconomic and geographical disparities in health outcomes, and inform future quality-related decisions about national policy for Medicaid health home programs by providing more uniform national data. Therefore, via this rule, we are mandating that both States and health home providers report on all Health Home Core sets measures, consistent with the Secretary's authority under sections 1945, 1945A, and 1902(a)(6) of the Act.

We therefore are revising the final rule as it pertains to the Child, Adult, and Health Home Core Sets as follows. We are removing proposed § 437.10(b)(1)(v), which provided States with additional time to report selected measures. We are replacing that proposed paragraph, in response to public comment, with language specifying that the frequency of reporting survey-based measures will be no more than annual. Additionally, we are revising § 437.10(c) to remove reference to phasing in measures and adding § 437.15(a)(1)(i) to require reporting on all measures in the 2024 Child Core Set and the behavioral health measures in the Adult Core Set. Mandatory reporting of the Health Home Core Sets is required only for an approved health home SPA that has an

[45] CMS released both the 2023 and 2024 Child and Adult Core Sets in November 2022 and the 2023 and 2024 section 1945 Health Home Core Set in December 2022.

effective date and has been implemented more than 6 months prior to the December 31st reporting deadline. This means that, for the States with approved health home program 1945 SPAs that were effective and implemented prior to June 30, 2023, the section 1945 Health Home Core Set would become mandatory in 2024. For both 1945 and 1945A SPAs that were effective and implemented starting July 1, 2023 through June 30, 2024, reporting the section 1945 and 1945A Core Set(s) would become mandatory in 2025.

Future new mandatory measures will be added to the Core Sets through the subregulatory process described in this rule. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters recommended that all States be required to report all Child and Adult Core Sets quality measures, as specified in statute at sections 1139A(a)(4)(B) and 1139B(b)(3)(B) of the Act, in the 2024 reporting year. Many commenters stated that they did not agree that the Secretary has the statutory authority to delay the reporting of selected measures for any of the Core Sets. One commenter recommended that mandatory State reporting should be required for all Child and Adult Core Sets required in statute, but that CMS could create an exceptions process for States that demonstrated that the requirement would generate unreliable data. This commenter requested that CMS ensure that States operating under such an exception report at least a standardized minimum set of measures to ensure valid comparisons across all States.

Response: Upon additional review, we agree that all of the measures on the Child Core Set and the behavioral health measures on the Adult Core Set should be subject to mandatory reporting in 2024, consistent with sections 1139A(a)(4)(B) and 1139B(b)(3)(B) of the Act.

Comment: Some commenters supported a phased-in approach to the inclusion of measures in mandatory reporting. One commenter recommended that CMS collect feedback from impacted interested parties on the most feasible reporting timeframe for specific measures while another recommended that States be allowed at least 2 years to begin reporting on new measures. One commenter recommended that the ''Screening for Depression and Follow-up Plan'' measure that is on both the Child and Adult Core Sets be required no earlier than the 2026 Core Sets. Another commenter recommended that CMS begin mandatory reporting of outcome measures using measures that only require administrative data and do not require supplementary data from other sources. Other commenters suggested several years of optional reporting for outcome and survey measures, and for measures that require EHR data.

Response: Upon additional review, we have determined that the statute requires that all of the measures on the Child Core Set and the behavioral health measures on the Adult Core Set should be subject to mandatory reporting in 2024. We recognize that some types of data collection are more burdensome than others, and States often struggle with collecting data for measures that depend on non-claims sources, hybrid specifications, or EHRs. We will provide technical assistance including one-on-one support to assist States with mandatory measures.[46] The outcomes of this process would be published in annual subregulatory guidance, as finalized in § 437.10(b) and (c) of this final rule.

Comment: One commenter recommended allowing States flexibility to determine the approach for hybrid- and survey-based measures based on their delivery system and not limiting reporting to one survey type, noting that a survey from an MCO that only serves beneficiaries with serious mental illness would not be comparable to other survey populations.

Response: We appreciate that there is considerable variability between States in how populations are served within their delivery systems and programs and how these populations are represented in State-level and health home program-level reporting. Despite these differences we believe the use of standardized quality measures, reporting guidance, and reporting is needed to accurately assess and compare data across populations and time and to allow for identification of more specific quality improvement opportunities. Use of alternative measures or survey types would undermine this goal. Therefore, we are not making any changes to § 437.10(b) in response to this comment.

Comment: Several commenters made recommendations regarding the survey-based measures in the Child and Adult Core Sets, such as those based on the CAHPS survey. A few commenters recommended that CMS require States to report data biennially (that is, once every 2 years) for all health outcome and survey-based measures. However, one commenter stated that they preferred annual reporting due to the loss of measure consistency, need to monitor quality improvement projects, and staffing and training issues. One commenter recommended that CMS consider the impact of declining response rates to surveys on Core Set reporting, and avoid duplicating efforts, noting that MCOs are also required to conduct CAHPS surveys. Some commenters encouraged CMS to explore alternative patient experience measures before phasing-in mandatory reporting of CAHPS-based measures.

Response: We intend to require annual reporting of health outcome and survey-based measures, which aligns with CHIP reporting requirements in section 2108(e) of the Act, as implemented through section 402 of CHIPRA. Specifically, Title XXI programs are required to annually submit to CMS data regarding access to primary and specialty services, access to networks of care, and care coordination provided under the State child health plan, using quality of care and consumer satisfaction measures included in the CAHPS survey. However, we appreciate the concerns raised regarding barriers to annual reporting of these measures and believe it is important for us to have the flexibility to reconsider frequency as needed based on State feedback. Therefore, we have revised § 437.10 to replace paragraph (b)(1)(v), which now specifies that survey-based measures will be required no more frequently than annually, allowing flexibility to respond to State needs in the future.

3. Populations Required for Mandatory Reporting

In section II.D.3. of the proposed rule, we explained that we interpret sections 1139A and 1139B of the Act to require that reporting for the Child Core Set include *all* beneficiaries covered by Medicaid and CHIP and to require that reporting for the behavioral health measures in the Adult Core Sets include *all* beneficiaries covered by Medicaid. We further explained that this would include beneficiaries enrolled in all Medicaid and CHIP delivery systems as well as services received in all applicable health care settings, such as hospitals, outpatient settings, Federally Qualified Health Centers (FQHCs), rural health clinics (RHCs), and facilities operated by IHS, by Tribes and Tribal Organizations under the Indian Self-Determination and Education Assistance Act, and by Urban Indian Organizations under Title V of the Indian Health Care Improvement Act.

[46] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

We also explained in section II.D.3. of the proposed rule that sections 1945(g), 1945(c)(4)(B), 1945A(g)(1)(B), and 1945(g)(2)(A)(i) of the Act, together with section 1902(a)(6) of the Act, support CMS guidance requiring State reporting on the Health Home Core Sets to include *all* beneficiaries enrolled in the applicable health home program. We further explained that this would include health home program beneficiaries receiving services through all Medicaid delivery systems, as well as health home program beneficiaries who received Medicaid-covered services in all applicable health care settings, such as hospitals, outpatient settings, FQHCs, RHCs, and facilities operated by IHS, Tribes and Tribal Organizations, and Urban Indian Organizations, during the measurement period. Further, we explained that we anticipated that health home programs would have to report on beneficiaries who have received Medicaid-covered health home services in FQHCs, RHCs, and facilities operated by IHS, Tribes and Tribal Organizations, and Urban Indian Organizations only if a beneficiary who is enrolled in the applicable health home program received Medicaid-covered health home services in one of these settings during the measurement period.

As explained in the proposed rule, we ultimately expected to require States to report on the populations discussed previously in this final rule for each Core Set through the annual reporting guidance; however, we did not propose to require this to begin with 2024 Core Set reporting in light of concerns about whether it would be feasible for States to begin reporting on all populations as soon as the rule would apply. Therefore, we proposed that the Secretary could, through the annual reporting guidance, phase in reporting on certain populations. Specifically, we proposed at § 437.10(b)(5) that annual reporting guidance would identify those populations for which States would be required to report measure data for a given year, and also proposed at § 437.10(c) that this annual guidance might provide that mandatory State reporting for certain populations of beneficiaries would be phased in over a specified period of time. These proposals applied to all Core Set reporting: Child, Adult, and Health Home. We solicited comment on how best to provide technical assistance to support States in reporting on all populations as well as on how long States may need to be able to report on all Medicaid, CHIP, and Health Home program beneficiary populations.

Comment: We received several comments supporting full mandatory reporting for all populations. However, many comments about these proposals noted concerns and challenges with reporting for specific populations of beneficiaries, such as those who are dually eligible for Medicare and Medicaid; those whose Medicaid or CHIP coverage is limited to payment of premiums and/or cost sharing, which may include those with private insurance; and those who receive services through Tribes and Tribal Organizations. We also received comments encouraging CMS to consider allowing States the ability to identify specific populations where reporting is difficult due to unique State circumstances.

Response: Although the majority of comments addressed concerns with including specific discrete populations in reporting of the Child and Adult Core Sets, we continue to believe that the intention of the statute is to provide the most comprehensive quality information on as much of the population as possible. Our view is that Congress' requirement for a mandatory reporting regime emphasizes their intent to ensure that all Medicaid and CHIP populations are aware of the quality of care in their state. Therefore, we have revised § 437.15(a)(4) of this final rule to require State reporting of mandatory Child and Adult Core Set measures for all Medicaid and CHIP beneficiaries, including those enrolled in fee-for-service and managed care, unless the Secretary specifies in annual guidance that the population is not required to be reported in accordance with § 437.10(b)(5) or CMS grants a State exemption for the population for one or more Child or Adult Core Set measures in accordance with § 437.15(a) of this rule. This differs somewhat in approach from the proposed rule, in which subregulatory guidance would identify populations for which States would be required to report; however, the final rule provisions are generally consistent with those commenters who supported comprehensive reporting of quality information for all Medicaid and CHIP populations, and with the proposed rule preamble's discussion of the proposed policy for the Child and Adult Core Sets. Rather than using subregulatory guidance to identify the populations for which States must report the Child and Adult Core Sets, as we proposed, we will instead use the guidance to identify specific difficult-to-report populations which will be, for a given reporting year, optional for states to include in reporting of the Child and Adult Core Sets.

With respect to the Health Home Core Sets, for the following reasons, we have determined that States with section 1945 or 1945A health home programs must report on all beneficiaries enrolled in the applicable health home program or programs, with no exceptions. Reporting on *all* populations served in health home programs will provide us with more accurate and comprehensive data that will help inform us of the effect of the health home benefits on coordination of care and aid us in identifying ethnic, racial and socioeconomic disparities. Also, reporting on all beneficiaries allows improved analysis of the quality of services rendered to persons enrolled in health home programs; such reporting can be utilized as a tool for the Annual Core Set Measures Workgroup when evaluating how a measure is contributing to the overall CMS mission of quality improvement for all populations served. Additionally, States will have Health Home Core Set measure data on all populations enrolled in the applicable health home from their health home providers, which are required to provide it to the State as a condition of payment under sections 1945(g) and 1945A(g) of the Act. Since the requirement for providers to report the data collected at the program level to States has been in effect from the beginning of both benefits, most states that have implemented the 1945 health home benefit have been voluntarily reporting on the health home core set for all populations. The 1945A health home benefit has not been in effect long enough to have data on a reporting cycle. Additionally, the population enrolled in health home programs is usually small and easily identifiable through existing data collected at the program level. Therefore, we have added § 437.15(a)(5) to the final rule, to require State reporting of sections 1945 and 1945A Health Home Core Sets measures for *all* beneficiaries enrolled in an approved health home program. This includes those beneficiaries that received Medicaid-covered health home services in FQHCs, RHCs, and facilities operated by IHS, Tribes and Tribal Organizations, and Urban Indian Organizations, if the beneficiary who is enrolled in the applicable health home program received Medicaid-covered health home services in one of these settings during the measurement period. Because reporting on the Health Home Core Sets is required for all beneficiaries enrolled in an approved health home

program, we also have revised § 437.10(b)(5) and (c) of this final rule to specifically reference only the Child and Adult Core Sets. The revisions to § 437.10(b)(5) required us to remove the wording, ''as described in paragraph (b)(5) of this section'' from § 437.10(b)(6) as annual reporting guidance on attribution rules applies to the Child, Adult, and Health Home Core Sets.

We address concerns about the feasibility of Child and Adult Core Sets reporting for specific populations in the final rule in two ways. First, because we recognize that there are certain populations for which all States potentially face difficulties in obtaining data, we are revising § 437.10(b)(5) and (c) of this final rule to provide that we will use the annual subregulatory guidance to identify specific populations which will be optional (that is, not mandatory) for States to include in reporting of the Child and Adult Core Sets for a given reporting year. For example, all States that commented on the proposed rule (including those States that currently participate in the Medicare-Medicaid Data Sharing program) requested more time to obtain, link, and analyze Medicare FFS claims and Part D events data. Further, States do not have access to the Medicare Part C data required to report on dually eligible beneficiaries who have enrolled in Medicare Advantage. Given these concerns with data access and experience, this could be an example of a population that the Secretary may exempt in subregulatory guidance issued prior to mandatory reporting. We note that these data access concerns do not impact the States' ability to report on Health Home Core Set measures since these measures do not require Medicare data. As stated previously, States will have Health Home Core Sets measure data on all populations enrolled in the applicable health home from their health home providers, which are required to provide it to the State as a condition of payment under sections 1945(g) and 1945A(g) of the Act. In addition, all the measures in the 2023 and 2024 section 1945 Health Home Core Set as well as all of the measures under consideration for the section 1945A Health Home Core Set can be reported using administrative claims data. Therefore, reporting on all populations for the Health Home Core Sets should not pose an excessive burden on States in the absence of any exceptions.

Second, as set forth in §§ 437.10(b)(5)(i) and 437.15(a)(4) and (6) of this final rule, we allow States to request a 1-year exemption from reporting for specific populations for one or more Child and/or Adult Core Set measures where those populations have not already been exempted by the Secretary for that year in the annual subregulatory guidance. The State would be eligible for such a 1-year exemption if it demonstrates to CMS that, despite reasonable efforts, it is not able to obtain access to data required to report for the population; for example, that it is unable to obtain needed third party data or to finalize a necessary data-sharing agreement between parties before the reporting deadline. The State must request the exemption from us by September 1st of the applicable reporting year, the exemption would be only for that year's reporting, and it would apply only to the specific population for which the State receives an exemption. We do not expect that this population-based exemption process will create an avenue for states to request an exemption from reporting one or more measure(s) in their entirety as most states are already reporting the majority of Core Sets measures for most of the beneficiaries in Medicaid and CHIP. The State will be required to explain why this exemption is necessary and provide a reasonable timeline of the actions underway to resolve the data access issue. In addition, as previously stated in this final rule, the State must demonstrate to us that it has made a reasonable effort to obtain the required data by the reporting deadline. We plan to respond to the State's request before the close of the mandatory reporting period to ensure that the State has time to complete reporting by December 31st. If we deny a State's request for exemption, the State will be expected to include the relevant population in that year's annual Child and Adult Core Sets reporting. Additionally, a State may re-apply in subsequent years to extend an exemption that has been granted. As stated in § 437.10(b)(5)(i), annual subregulatory guidance will provide information about how States can request an exemption.

Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported the requirement that States include populations that are harder to report in Core Set reporting, as outlined in the proposed rule, including those who are dually eligible for Medicare and Medicaid, those who use long-term services and supports, people with substance use disorders, and people in FFS Medicaid, including in States that enroll most people in managed care.

Response: We thank these commenters for their support of required reporting for these populations.

Comment: Multiple commenters requested additional clarification from CMS on how States should allocate beneficiaries who experience gaps in coverage or who are enrolled in multiple plans during the reporting period. Specifically, in some States, commenters noted that FFS enrollment is temporary until a beneficiary selects a managed care plan. In other States, FFS populations may comprise a very small percentage of total Medicaid enrollment. The commenters recommended that CMS consider whether the inclusion of the beneficiaries temporarily enrolled in FFS in Core Set reporting is an appropriate use of significant State resources.

Response: As discussed in section II.D.3. of this final rule, we interpret sections 1139A and 1139B of the Act to require reporting of *all* beneficiaries covered by Medicaid and CHIP for the Child Core Set, and to require reporting for the behavioral health measures in the Adult Core Set of *all* beneficiaries covered by Medicaid. Additionally, as discussed previously in this section of this final rule, we are requiring in this final rule that reporting for the Health Home Core Sets include *all* beneficiaries enrolled in the applicable health home program. Attribution of performance and quality data poses challenges for the health care field, and Medicaid and CHIP in particular, as it requires striking a balance between the person-centered goal of measuring quality of care for a beneficiary regardless of delivery system and feasibility for providers, plans, health systems, and States. Our intent in implementing mandatory reporting requirements is for the data collected to be as inclusive of all beneficiaries as possible. However, when developing annual guidance, we will consider what distinctions between delivery systems are meaningful, being mindful of short-term transitions.

Comment: Multiple commenters supported a phased-in approach to the inclusion of populations in mandatory reporting but provided different recommendations about the approach CMS should take. One commenter recommended that CMS collect feedback from affected and interested parties on the most feasible reporting timeframe for specific populations. Another commenter requested that States have the flexibility to make the decisions about phasing in reporting of populations that are challenging to report on a timeframe that is feasible for each State. One commenter recommended that phasing in reporting for any given population should be limited to no more than 3 years, while

others noted that 2 to 5 years is the minimum amount of time needed. One commenter recommended that CMS extend the phase-in period beyond 5 years, proposing up to 7 years to phase in fully reporting all measures for all populations. Several commenters recommended allowing more time before CMS phases in mandatory reporting for other populations, such as dually eligible beneficiaries; recommendations varied from as soon as 3 years to 10 years.

Response: Commenters had varying preferences regarding the amount of time that we should provide for phasing in mandatory reporting on specific populations; some commenters recommended that we give States the flexibility to decide what populations they are able to report on, based on their unique circumstances. While reporting on standardized populations will help us achieve data consistency across States and provide actionable data to identify disparities and support efforts to improve the quality of health care, we recognize, based on the range of years supported in public comments, that the ability of States to report on the Child and Adult Core Sets for certain populations may vary, and there are unique circumstances which may result in States' inability to report on certain populations in a given year. As discussed previously in this final rule, we have revised § 437.10(b)(5) and (c) to specify that the Secretary will identify in annual guidance the populations for which States may voluntarily, but are not required to, report the Child and Adult Core Set measures for a specific year. As further discussed previously in this final rule, this same flexibility is not needed for the Health Home Core Sets due to the ready availability of provider data, small population size, and ease of measure calculation. In §§ 437.10(b)(5)(i), 437.15(a)(4), and (6) we also added an opportunity for States to request a 1-year exemption from reporting mandatory populations for the Child and Adult Core Sets for one or more Child or Adult Core Set measures if the State demonstrates an inability to obtain access to data required to report on the measure(s) for the population—for example, if a State is unable to obtain a necessary data-sharing agreement between parties before the reporting deadline. We will consider renewing exemptions for specific populations on an annual basis. Additionally, we revised § 437.15(a)(4) to specify that mandatory reporting would include both fee-for-service and managed care delivery systems unless the population is otherwise specified by the Secretary pursuant to § 437.10(b)(5) or the State has received an exemption. We will work collaboratively with States to provide the technical assistance and reporting guidance necessary to support improvements in reporting for certain populations.

We have also revised §§ 437.10(b)(5), (c), and 437.15(a)(4) of this final rule to specifically reference only the Child and Adult Core Sets. This is because, as discussed previously, under this final rule, Health Home Core Set reporting must include reporting on all beneficiaries enrolled in an approved health home program.

Comment: Multiple commenters noted concerns with accessing claims data for beneficiaries who may be enrolled in Medicaid only for premium assistance programs. Multiple commenters requested that CMS provide clarification that the rule would not apply to individuals who have both Medicaid coverage and private insurance coverage, as the Medicaid agency would not have access to claims information from the member's private plan.

Response: We agree with the commenters that reporting Child and Adult Core Set measures for beneficiaries whose Medicaid or CHIP coverage is limited to payment of private insurance premiums and/or cost sharing may be challenging, as States currently do not have consistent access to data needed from the liable third-party payer, and as discussed previously in this final rule, we are revising § 437.10(b)(5) such that the Secretary will identify in annual guidance populations for which States may, but are not required to, report the Child and Adult Core Set measures. We will work with States to determine reporting feasibility and the technical assistance needed for mandatory Child and Adult Core Sets reporting on such beneficiaries, and will update reporting guidance and mandatory reporting requirements based on these assessments. Reporting for populations who are dually eligible for Medicare and Medicaid is discussed below. We further note that the process for delaying reporting under § 437.10(b)(5) does not apply to the Health Home Core Sets as discussed previously in this final rule. As discussed previously, States are expected to have the data they need to report on the Health Home Core Sets from health home providers, and therefore, are not expected to experience the challenges in reporting for beneficiaries whose Medicaid or CHIP coverage is limited to payment of private insurance premiums and/or cost sharing discussed above.

Comment: Several commenters opposed mandatory State reporting for the dually eligible population and suggested that CMS should be the responsible party for reporting on the dually eligible population as Medicare is the primary payer for most benefits and services for these beneficiaries. A few commenters recommended that CMS should limit mandatory State reporting for dually eligible beneficiaries to delivery systems or measures where the State is directly accountable. One commenter recommended limiting reporting to States that operate Statewide, fully-integrated models for dually eligible beneficiaries (for example, fully integrated dual eligible special needs plans), and one commenter recommended limiting reporting on Core Set measures for dually eligible beneficiaries to measures for which the State is directly accountable so that the quality reporting on dually eligible beneficiaries is reflective of the payer of services.

Response: We recognize the concerns about States' ability to report on the dually eligible population when States are not the primary payer for most health care services for this population. We disagree that States should not report on all dually eligible individuals in the States' reporting of Core Sets measures. Dually eligible individuals experience the health care system and incur health outcomes as individuals, regardless of whether Medicare or Medicaid pays for the service. The purpose of the Child and Adult Core Sets is to measure the overall national quality of care for beneficiaries, which is not limited to services reimbursed by Medicaid or CHIP. The main goal of the health home programs is to improve health outcomes for beneficiaries through care coordination that is intended to better link primary, behavioral health, and long-term services and supports for beneficiaries served by the health home program. The Health Home Core Sets will be used for ongoing monitoring and evaluation purposes across all State health home programs to measure this goal. As discussed previously, States are expected to have the data they need to report on the Health Home Core Sets from health home providers and therefore are not expected to experience challenges in reporting for dually eligible individuals. We recognize that States must obtain, link, and analyze Medicare data in order to report the Child and Adult Core Sets of measures for fee-for-service beneficiaries, and that States do not have access to encounter

data for Medicare Part C (Medicare Advantage), and we expect to phase in required reporting of Child and Adult Core Set measures for dually eligible beneficiaries. We will include information, including available technical assistance, on mandatory Child and Adult Core Sets reporting for this population in annual reporting guidance. Since all States that commented on the proposed rule, including those States that currently participate in the Medicare-Medicaid Data Sharing Program, requested more time to obtain, link, and analyze Medicare data, we will work with States and interested parties to identify the timeframe for which mandatory Child and Adult Core Sets reporting for dually eligible beneficiaries will be required. Additionally, we will continue to assess whether we can use T–MSIS or other alternative data sources to calculate Child, Adult, and Health Home Core Sets measures on behalf of States.

Comment: Several commenters expressed concern about access to and the availability of assistance with using the Medicare FFS claims and Part D events data that are needed to report on dually eligible beneficiaries and were concerned that States would require extensive resources to utilize the data. They further commented that CMS is disadvantaging States, as this data is very difficult to obtain and out of their control. A few commenters encouraged CMS to facilitate State participation in the Medicare-Medicaid Data Sharing Program. A commenter recommended CMS establish a standardized data license/sharing agreement to facilitate Medicare data requests for the dually eligible population.

Response: Since 2011, we have provided States access to Medicare FFS claims and Part D events data for dually eligible beneficiaries, including dually eligible beneficiaries whose Medicaid or CHIP coverage is limited to payment of premiums and/or cost sharing (also known as partial-benefit dually eligible beneficiaries), free-of-charge via the Medicare-Medicaid Data Sharing Program. Information on the Medicare-Medicaid Data Sharing Program, including how to request data and the standard data sharing agreements, is available through the State Data Resource Center. We acknowledge that not all States currently request Medicare claims and events data, and that those States that do not currently request Medicare claims and events data may need additional time to request and effectively utilize these data. We also acknowledge that the Medicare-Medicaid Data Sharing Program does not currently make available Medicare Part C encounter data, as discussed in the response below. Since all States that commented on the proposed rule, including those States that currently participate in the Medicare-Medicaid Data Sharing Program, requested more time to obtain, link, and analyze Medicare FFS data, and in light of the systematic Medicare Part C data access challenges, we anticipate that the Secretary's subregulatory guidance issued under § 437.10(b) may specify that mandatory Child and Adult Core Sets reporting will not be required initially for dually eligible beneficiaries. This approach will address concerns for States that are not currently requesting Medicare claims and events data, providing them additional time to gain familiarity with the available claims and events data. Subregulatory reporting guidance will also consider care delivery systems and data availability. Specific to Health Home Core Sets, States collect data from the provider at the program level for this population to inform the health home measures, and therefore the health home measures do not rely on Medicare claims data. Health home programs are an optional State benefit, and there is the possibility that a dually eligible beneficiary could be enrolled in both Medicare and a State health home program if the dually eligible beneficiary has full Medicaid coverage (that is, a ''full-benefit dually eligible beneficiary''). If a full-benefit dually eligible beneficiary is enrolled in both a State health home program and Medicare, the provider would submit data for health home measures to the State, and the State would include this population in Health Home Core Sets reporting. We will consider implications of data access when reviewing measures for possible addition to the Health Home Core Sets in future years.

Information on the Medicare-Medicaid Data Sharing Program, including on how to request data and the standard data sharing agreements, is available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/StateAccesstoMedicareData* or by contacting the State Data Resource Center at *https://www.statedataresourcecenter.com/home/contact-us.* We will take under advisement the commenters' recommendations on additional technical assistance and resources for using Medicare FFS data, and we will consider Medicare data availability and ease of use when determining the Child and Adult Core Sets reporting schedule for the dually eligible population in general.

Comment: Multiple commenters supported provision of technical assistance to States on inclusion of those dually eligible for Medicare and Medicaid and recommended that CMS provide open-source tools, opportunities for shared learning, assistance in developing data infrastructure, guidance on how to link Medicaid and Medicare data, data infrastructure, model analysis with T–MSIS data, and standardized Medicare data packages tailored to Core Set analysis. A commenter recommended considering the work of the NQF Measure Application Partnership (MAP) Dual Eligible Beneficiaries Workgroup when considering measures for the Core Sets and data availability.

Response: We plan to provide technical assistance on Child, Adult, and Health Home Core Sets reporting for dually eligible beneficiaries and will take these ideas into consideration when developing technical assistance resources and learning opportunities.

Comment: Several commenters were concerned about the lack of available Medicare Part C encounter data. These commenters explained that States cannot report on dually eligible beneficiaries enrolled in Medicare Part C without these data.

Response: We recognize that we do not currently make available Medicare Advantage data to States free-of-charge via the Medicare-Medicaid Data Sharing Program. We are looking into how to address this issue. We do not intend to require that States report Child and Adult Core Set measures on dually eligible beneficiaries enrolled in Medicare Part C (that is, in Medicare Advantage) until such data are available. Specific to Health Home Core Sets, States collect data from the provider at the program level for this population to inform the health home measures, and therefore the health home measures do not rely on Medicare claims data. We will consider implications of data access when reviewing measures for possible addition to the Health Home Core Sets in future years.

Comment: One commenter expressed concern with reporting of Medicaid FFS beneficiaries in their State, as they may not meet continuous enrollment requirements for quality measurement. Another commenter noted that there is a significant burden for including Medicaid FFS beneficiaries in State-wide reporting of hybrid measures.

Response: The purpose of the Child and Adult Core Sets, as suggested by sections 1139A and 1139B of the Act, is

to measure the overall national quality of care for beneficiaries, monitor performance at the State level, and improve the quality of health care. The main goal of the health home programs is to improve health outcomes for beneficiaries through care coordination that is intended to better link primary, behavioral health, and long-term services and supports for beneficiaries served by the health home program.[47] [48] The Health Home Core Sets will be used for ongoing monitoring and evaluation purposes across all State health home programs to measure progress towards this goal. While we recognize the additional burden to States that may not currently include Medicaid FFS beneficiaries in their reporting, in order to improve the quality of care delivered to all beneficiaries, States must include in reporting the entire population covered by Medicaid and CHIP (or served by the applicable health home program), including Medicaid FFS beneficiaries, except to the extent the Secretary exempts a population from reporting for Child and/or Adult Core Sets measures in annual guidance or grants a state exemption for a specific population for a specific reporting year, as discussed in detail previously in this section. We have revised § 437.15(a) accordingly. The vast majority of measures on the Core Sets (84 percent of the 2023 and 2024 Child Core Set and behavioral health measures on the Adult Core Set can be calculated using administrative claims or survey data. One hundred percent of the 2023 and 2024 section 1945 Health Home Core Set as well as 100 percent of the measures under consideration for the section 1945A Health Home Core Set) can be calculated using administrative claims data. We are assessing the resources and technical assistance to support States in using other data sources more widely. In order to be included in Core Set reporting, beneficiaries must still meet enrollment requirements for quality measurement, which are established by the measure stewards for each measure and based on a beneficiary's continuous enrollment in Medicaid and CHIP. Additionally, for Health Home Core Sets a beneficiary must also be enrolled in an approved health home program. FFS or other beneficiaries who do not meet the enrollment requirements for a given measure would not be included in a State's report.

Comment: One commenter suggested CMS test the validity of mandatory measures that have been expanded to include additional populations, specifically populations that may be more difficult to include, prior to public reporting, and that CMS ensure that risk adjustment models of mandatory measures are robust enough to provide fair comparisons when including expanded populations. This commenter further recommended that CMS work with measure developers to evaluate the fit of the risk adjustment models for mandatory measures prior to reporting results publicly to ensure they generate meaningful information and allow for fair comparisons.

Response: We anticipate that our Core Set reporting guidance will align with measure steward technical specifications with regard to defining the populations included in the measure and to risk adjustment. If the measure steward includes risk adjustment for a measure on the Core Sets, we will include risk adjustment for that measure. We work with measure stewards to adapt measures for State level reporting and provide appropriate reporting guidance. The issue of validity testing of mandatory measures is outside the scope of this rulemaking.

Comment: Several commenters noted that decisions about whether to submit health care data necessary to calculate Core Set measures for beneficiaries receiving care from Indian Health Care Providers (IHCPs) rest with the Tribes and Tribal Organizations, and any CMS rules about data completeness must respect Tribal sovereignty and Tribes' decisions about whether to submit health care data. One commenter noted that the addition of health care facility data from IHS, Tribes, and Tribal Organizations would require significant technical assistance and funding from CMS to facilitate the development of needed infrastructure to support these providers' readiness to capture required data elements, and to assist with data transmission.

Response: We understand that Tribes and Tribal providers take seriously their role in protecting the confidentiality of American Indian/Alaska Native (AI/AN) data and note that State Core Set data is de-identified before it is submitted to us for Core Set reporting. We also recognize that States enter into individual contractual and data use agreements with Tribes and Tribal providers that may affect the availability of Tribal data for Core Sets reporting. States might choose to require their Medicaid providers to report certain data to the State as a condition of receiving Medicaid payment, if doing so would help the State comply with the Core Sets reporting requirements. We strongly encourage States to consult with Tribes and to coordinate with IHS, and Tribes and Tribal Organizations, to discuss reporting of Child and Adult Core Set measures regarding the services provided by IHS and Tribal health care providers in their State. Collaborative relationships between government entities and Tribes are essential to responsible and effective data use and to understanding and addressing the gaps in these data,[49] which limit analyses that support public health decision-making in AI/AN communities.[50] Any delay of reporting data for AI/AN beneficiaries will impede efforts to improve health outcomes for these populations, and we encourage Tribes to report Core Set data to their respective States to help improve the quality of their State's Medicaid program, and ultimately the quality of health care provided to AI/AN individuals.

As discussed previously in this final rule, States are required to report Child and Adult Core Sets quality measure data for all populations, unless a population is identified as optional in annual subregulatory guidance to be issued by CMS, and States may request a 1-year exemption from reporting mandatory populations for one or more measures on the Child and Adult Core Sets if the State demonstrates an inability to obtain access to data, which may include for example, an inability to obtain needed third-party data or to finalize a necessary data-sharing agreement between parties before the reporting deadline. Moreover, this final rule requires States and health home providers to report data on all populations enrolled in the applicable health home. If Tribes or Tribal Organizations are providing section 1945 or section 1945A health home services, sections 1945 and 1945A of the Act require them to report data to the State as a condition of payment for these health home services, as discussed in more detail previously in this final rule.

E. Application of the Child and Adult Core Sets to CHIP

As discussed in section II.E. of the proposed rule, in §§ 437.15(b), 457.700 and 457.770 we proposed the following requirements for CHIP programs: to require that separate CHIPs report on all measures in the Child Core Set in

[47] *https://www.medicaid.gov/resources-for-states/medicaid-state-technical-assistance/health-home-information-resource-center/index.html.*

[48] *https://www.medicaid.gov/resources-for-states/medicaid-state-technical-assistance/health-home-information-resource-center/1945a-health-home-resources/index.html.*

[49] *https://aspe.hhs.gov/reports/gaps-strategies-improving-american-indianalaska-nativenative-american-data#TOC.*

[50] *https://www.gao.gov/products/gao-22-104698.*

accordance with the requirements outlined in the proposed rule and include all CHIP beneficiaries in State reporting, including pregnant individuals receiving child health assistance coverage for the duration of pregnancy in States that elect to provide coverage through the group known as the 'unborn option'. Separate CHIP programs are encouraged, but not required, to report on the measures in the Adult Core Set.

We received public comments on the application of mandatory reporting to CHIP, and in general, commenters supported the proposed process. We are finalizing these provisions with revisions to §§ 437.15(b)(1) and 457.770(c) as discussed in section II.E.1. of this final rule. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported CMS' proposal, in section II.E. of the proposed rule, to include pregnant individuals receiving coverage under CHIP, including those provided CHIP child health assistance for the duration of pregnancy (also referred to as the ''unborn option''), in the mandatory reporting requirements for the Child Core Set, if the pregnant individual meets the age parameters for the measures. One commenter requested guidance on whether States would be required to report quality measures for pregnant individuals receiving coverage through the option to extend special CHIP child health assistance for the duration of pregnancy and whether States would be required to include this population in Adult Core Set reporting.

Response: We appreciate the support from these commenters. We are finalizing the mandatory reporting requirements as proposed in § 457.770(a) to require States to include this population of CHIP beneficiaries when reporting on quality measures in the Child Core Set. States that provide coverage for the duration of pregnancy under CHIP would be required to include this population in reporting of the Child Core Set if the participants meet the age parameters for the measures referenced in § 457.770(a) of this final rule. Reporting on the Adult Core Set is encouraged, but voluntary, for beneficiaries enrolled in CHIP in § 457.770(b) of this final rule.

Comment: One commenter recommended that individuals receiving coverage under CHIP should also be included in reporting for any measures from the Adult Core Set that the State reports on for their CHIP population.

Response: Section 1139B(b)(3)(B) of the Act makes reporting by States on the Adult Core Set measures mandatory only with respect to the quality of behavioral health care provided to Medicaid-eligible adults. As a result, States are encouraged, but not required, to report on the measures in the Adult Core Set for beneficiaries in separate CHIP programs as per § 457.770(b) of this final rule.

Comment: One commenter requested guidance on whether CMS would give States the option to report by combining the Child Core Set State-level data and section 1945 health home program data.

Response: We will provide technical assistance and further details on how small population sizes should be handled through our reporting guidance. Under this final rule, data would be reported separately at the health home program level for the Health Home Core Sets and the State level for the Child and Adult Core Sets. Given these different denominators for these obligations, we do not plan to combine these reporting requirements.

Comment: One commenter noted that their State enrollment under the special CHIP child assistance option for pregnant individuals is very low and reporting on it will have little impact on the overall rate. Another commenter noted that many individuals who receive special CHIP child assistance for pregnant individuals would not meet the eligibility requirements for reporting, such as receiving CHIP for the duration of the pregnancy or age requirements, and as such, collection of the data may not be a good use of data resources.

Response: While the special CHIP child assistance for pregnant individuals is reflective of a very specific and relatively small population, we believe it is important to gather data for as many populations as possible. In some cases of small population sizes, core set measure data would not be reported separately, but would be included in reports of larger populations. We will provide technical assistance and further details on how small population sizes should be handled through our reporting guidance. We will follow data suppression policies for measure stewards in addition to our Cell Size Suppression Policy such that if sample sizes are too small, data will not be publicly reported to avoid a potential violation of privacy.[51]

Comment: One commenter encouraged CMS to adhere to measure steward specifications and urged that if CMS expands the denominator beyond those specifications, such as including individuals without 12 months of data, CMS should assess the validity and actionability of the measures.

Response: We will take this feedback into consideration when developing Core Set reporting guidance. We will provide technical assistance and further details on enrollment requirements for inclusion of beneficiaries in Core Set reporting through our reporting guidance. In order to be included in Core Set reporting, beneficiaries must still meet enrollment requirements for quality measurement, which are established by the measure stewards for each measure and based on a beneficiary's continuous enrollment in Medicaid and CHIP. This would ensure that the State has enough time to render services during the measurement period and would be based on a beneficiary's enrollment date in Medicaid and CHIP (not inclusive of retroactive eligibility). In making measure adaptations, we work closely with measure stewards to develop reporting guidance and to make as few adaptations to the technical specifications as possible.

1. Separate Reporting of the Child Core Set for Medicaid and CHIP Beneficiaries

As discussed in section II.D.4. of the proposed rule, in §§ 437.15(b) and 457.770(c), we proposed that States with a separate CHIP report on Child Core Set measures in three categories: Medicaid and CHIP combined; Medicaid inclusive of CHIP-funded Medicaid expansion (Titles XIX and XXI); and separate CHIP (Title XXI). We also proposed that reporting guidance would include attribution rules, to specify in which program (Medicaid or CHIP) a State would count a child who transitioned between programs within a reporting period.

In response to comments received, we have revised §§ 437.15(b)(1)(i) and (ii), and 457.770(c), to specify that States with separate CHIP programs report on the Child Core Set measures in two categories instead of three as originally proposed: (1) separate CHIP (Title XXI) and (2) Medicaid inclusive of CHIP-funded Medicaid expansion (Titles XIX and XXI). Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported the proposed rule proposal to require adherence to the same reporting guidance for Medicaid (funded through Title XIX and Title XXI) and separate CHIP programs, and recommended that the proposed language at § 437.15(b) be revised to clearly articulate that States with a separate CHIP program report on

[51] CMS Cell Suppression Policy: *https://www.hhs.gov/guidance/document/cms-cell-suppression-policy.*

Child Core Set measures in three categories: Medicaid and CHIP combined; Medicaid inclusive of CHIP-funded Medicaid expansion (Titles XIX and XXI); and separate CHIP (Title XXI). Several other commenters recommended that CMS simplify the reporting categories to instead only require reporting on two categories for Medicaid inclusive of CHIP-funded Medicaid expansion (Titles XIX and XXI) and separate CHIP (Title XXI).

Response: In response to public comment, we have revised §§ 437.15(b)(1)(i) and (ii), and 457.770(c), to specify that States with separate CHIP programs will be required to report on the Child Core Set measures in two categories, instead of three as originally proposed. The category of Medicaid inclusive of CHIP-funded Medicaid expansion includes all Medicaid enrollees, regardless of whether they are funded by Title XIX or XXI. We will aggregate the separate CHIP and Medicaid inclusive of CHIP-funded Medicaid expansion data to create the Medicaid and CHIP combined category, alleviating the burden on States to create and report that data. We believe the change from the three originally proposed reporting categories to the two reporting categories described previously in this final rule maintains the intent of the proposed rule.

Comment: Several commenters did not support separate reporting of children in Medicaid and CHIP. They thought that it added little value and would result in an additional reporting burden, as combined reporting more closely aligns with how services are provided. Instead, one commenter recommended combining reporting for Medicaid and CHIP, and using attribution to determine to which program beneficiaries should be assigned. One commenter recommended CMS allow aggregate reporting to align with current State practices, while another commenter asked if separate or combined reporting of CHIP could be determined at the State level.

Response: Separate CHIP programs have different service requirements than Medicaid. Therefore, we expect that results for certain measures could vary within States for separate CHIP and Medicaid. We believe these differences are important to document, and therefore are maintaining the requirement at §§ 437.15(b) and 457.770(c) that States with a separate CHIP report separate CHIP data separately from Medicaid data. Meanwhile, we have updated the reporting categories to incorporate both Title XIX and Title XXI-funded Medicaid under one category to reduce State burden and to reflect the fact that the source of funds (Title XIX or Title XXI) providing the Federal match for a child enrolled in Medicaid does not impact which or how services are provided. We will also aggregate the separate CHIP and Medicaid data to obtain the combined Medicaid and CHIP results, rather than requiring States to report the combined results, to reduce State burden.

Comment: One commenter suggested that any separate CHIP reporting should be limited to administrative measures that are in the control of MCOs.

Response: The Core Sets are State-level and health home program-level reporting programs, not managed care or health plan-level reporting programs. One of the goals of mandatory reporting is to provide inclusive data on quality and performance for all beneficiaries, regardless of delivery system. We will provide technical assistance to address the needs of States and State partners to report the Core Sets.

Comment: Several commenters noted that if States were required to report results for Medicaid and CHIP separately, a separate CAHPS survey for CHIP would be required. Multiple surveys would result in significant cost increases, require additional time to implement, and increase the potential for insufficient sample sizes.

Response: We will take this feedback into consideration as part of the guidance process that is discussed in the rule. Section 2108(e)(4) of the Act requires states to collect and report CAHPS survey results for Title XXI CHIP programs (see CHIPRA section 402(a)(2)) as part of their annual reports to the Secretary. Reporting CAHPS survey results separately currently is encouraged for voluntary Core Set reporting, and several States successfully do so. We note that previous CMS guidance outlines how States can sample and report CHIP and Medicaid results separately for CAHPS.[52]

Comment: One commenter supported the proposal that CMS include attribution rules in reporting guidance for counting children who move between Medicaid and separate CHIP. One commenter recommended that States be required to include children that meet continuous enrollment criteria in reporting for CHIP, as is required for Medicaid reporting and enrollment criteria, in order to allow for better comparisons. This commenter requested a separate population category for enrollees transitioning from Medicaid to CHIP if CMS were to require reporting on this group, noting that combining these data for children who transition between programs would be burdensome. Multiple commenters acknowledged the need to include children in Child Core Set reporting who transition between Medicaid and CHIP in order to promote consistency and prevent duplicative reporting. Some commenters raised concerns that inconsistencies in Medicaid and CHIP requirements could make it difficult to combine these two groups for reporting.

Response: We plan to provide detailed guidance about attribution rules in the annual reporting guidance required under § 437.10(b), as finalized in § 437.10(b)(6) of this rulemaking with minor changes. We note the importance of capturing data for the population of children who transition between Medicaid and CHIP, given the implications of insurance churn on health care quality.

Comment: One commenter noted that some States with small separate CHIP programs may have difficulty reporting on their CHIP population and requested technical assistance and support from CMS to address data collection and calculation challenges.

Response: We appreciate these comments and concerns and will provide technical assistance to meet the needs of States and State partners.[53]

F. Ensuring Compliance With the Mandatory Reporting Requirements

As discussed in section II.F. of the proposed rule, in § 437.20, we proposed to require that States submit a Medicaid SPA attesting that the State agency would report on the Child, Adult, and Health Home Core Sets in accordance with the requirements in the final rule. Health Home SPAs would also include an attestation that the State will require its providers of health home services to report to the State on the measures that the State has to report. With these attestations in the State plan, we would have authority under section 1904 of the Act to withhold Federal Medicaid payments, in whole or in part, if an agency fails to comply with the Medicaid reporting requirements.

We also proposed changes to § 433.112 which would apply existing Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, Breach Notification, and Enforcement Rules under 45 CFR parts 160 and 164, the HIPAA electronic

[52] Fact Sheet 2012: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/cahpsfactsheet.pdf.*

[53] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

transactions standards under 45 CFR part 162, and the health information technology standards under 45 CFR part 170 subpart B to the Core Sets.

We received public comments on compliance requirements, and in general, commenters supported the proposed process. We are finalizing these provisions with a minor wording change to § 437.20(a) to clarify that reporting on Health Home Core Sets measures applies to all populations served by the health home and other minor wording changes to clarify cross-references within the same subpart. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported the proposed standards that States must meet to qualify for enhanced Federal matching funds for Medicaid systems and encouraged the Secretary to use this authority to enforce compliance with mandatory reporting of the Core Set measures. One commenter asked for more information on Federal matching funds for systems.

Response: We thank the commenters for their support for our proposal to use these Federal authorities to enforce compliance with Core Set requirements. CMS regulations at 42 CFR part 433, subpart C specify conditions that State Medicaid systems must meet in order for the State's expenditures on mechanized claims processing and information retrieval systems to be matched at the 90 and 75 percent rates described in section 1903(a)(3)(A)(i) and (B) of the Act. These conditions include industry standards described in § 433.112(b)(12), which with the publication of this final rule now include standards and protocols for reporting on the Child and Adult Core Sets and the Health Home Core Sets, as relevant to the specific State Medicaid system or module. Under these regulations, which implement section 1903(a)(3)(A)(i) and (B) of the Act, enhanced FFP is available at 90 percent for State expenditures for the design, development, and installation (including of enhancements) of qualifying State Medicaid systems, and at 75 percent for State expenditures for operations of such systems, once approved by CMS, in accordance with applicable Federal requirements.[54] Furthermore, in accordance with regulations at §§ 433.117 and 433.119, we may not approve replacement State systems or may not reapprove existing State systems if the State does not meet Core Set reporting requirements that are now described in § 433.112(b)(12) and cross-referenced in § 433.116(c), which means that we would not approve or reapprove a Federal matching percentage of 75 percent under section 1903(a)(3)(B) of the Act for such systems.[55]

Additional information about FFP rates for State Medicaid system design, development, and installation (including of enhancements) and operation available under section 1903(a)(3)(A)(i) and (B) of the Act can be found in the Mechanized Claims Processing and Information Retrieval Systems regulations at 42 CFR part 433, subpart C. Separately, under section 1903(a)(3)(A)(iii) of the Act, State expenditures for Medicaid system development and modifications necessary for collecting and reporting on child health quality measures are matched at the State's FMAP rate as defined in section 1905(b) of the Act.

Comment: Some commenters suggested CMS should develop more explicit guidance outlining specific, graduated enforcement mechanisms for States that remain out of compliance with quality reporting requirements, in order to ensure clear enforcement action is taken against States and other entities that fail to comply and encourage State corrective action.

Response: As noted previously in this final rule, States will be required to submit a Medicaid SPA attesting that the State agency will report on the Child, Adult, and Health Home Core Sets in accordance with the requirements in 42 CFR part 437, as finalized in § 437.20. Since States have to attest that they will meet the mandatory reporting requirements, we will be able to withhold Federal Medicaid payments, in whole or in part, from a State that is non-compliant with these reporting requirements in accordance with section 1904 of the Act and implementing regulations at 42 CFR 430.35. We will be able to withhold Federal funds under Title XXI for noncompliance with the reporting requirements for CHIP in accordance with § 457.204 once § 457.770 is codified. The requirement at § 437.20 to submit a SPA does not apply to the CHIP agency. The CHIP State plan already includes an attestation in section 9.4 that ''the State assures it will collect all data, maintain records and furnish reports to the Secretary at the times and in the standardized format that the Secretary requires.'' All States have made this attestation in the current version of their State plan. Graduated enforcement mechanisms for compliance with Core Sets reporting requirements due to issues with State data systems will align with existing CMS policy regarding State corrective action plans.[56]

Comment: Several commenters supported the proposed requirement that States amend their State Plans to indicate that they would report on the Core Sets in order to give CMS clear authority to enforce the Core Set reporting requirements by withholding Federal Medicaid payments under section 1904 of the Act in the event of noncompliance by a State. One commenter requested clarification on the deadline for submission of the SPA.

Response: We appreciate the support for this proposed Medicaid requirement at § 437.20, which we are finalizing as proposed in this rulemaking. We plan to discuss details of changes to the SPA, including the deadline for submission, in annual reporting guidance.

Comment: Several commenters suggested that requiring Health Home programs to submit Core Set measures to the State as a condition of receiving payment, in addition to the State reporting to CMS, is duplicative and redundant.

Response: While we appreciate the submission of these comments, the proposed rule implements statutory reporting requirements that health home providers must meet, as a condition of payment, under sections 1945(g) and 1945A(g)(1) of the Act. If a Health Home provider is submitting all required data into a State-based system that the State is then using to calculate and report the Health Home Core Sets measures to CMS, that would satisfy the statutory requirement for providers under sections 1945(g) and 1945A(g)(1) of the Act.

Comment: A few commenters recommended that CMS change 42 CFR 431.16, which implements section 1902(a)(6) of the Act, to specify that the State plan requirements include the reporting of the Core Sets and underscore the importance of State compliance with Core Sets reporting.

Response: Section 431.16 requires that States comply with all reporting requirements established by the Secretary and that their State plans reflect that the State will do so. Section

[54] See section 1903(a)(3)(A)(i) and (B) of the Act, 42 CFR 433.15(b)(3) and (4), subpart C of 42 CFR part 433, and State Medicaid Director Letter (SMDL) #22–001.

[55] Medicaid Enterprise Systems Compliance and Reapproval Process for State Systems with Operational Costs Claimed at the 75 Percent Federal Match Rate CIB at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib052423.pdf.*

[56] Medicaid Enterprise Systems Compliance and Reapproval Process for State Systems with Operational Costs Claimed at the 75 Percent Federal Match Rate CIB at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib052423.pdf.*

431.16 does not list any specific reports that States are required to submit, and we do not believe it would be appropriate to single out Core Sets reporting alone. Further, it is not necessary to do so, as the current language of § 431.16 is broad enough to encompass these newly finalized Core Sets reporting requirements (as they pertain to Medicaid), and because § 437.20 of this final rule sets forth the requirement for States to submit a State plan amendment attesting to compliance with the Core Sets reporting requirements.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purpose of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection must be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our August 22, 2022 (87 FR 51303) proposed rule, we solicited public comment on each of these issues for the following provisions that contain information collection requirements. As stated in section II. of this final rule, we received 93 public comments on the proposed rule, but only one of those comments was related to the rule's collection of information requirements. The comment and our response can be found in section III.C. of this preamble.

A. Wage Estimates

Private Sector, States, and Territories: To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2022 [57] National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). Table 1 presents BLS' mean hourly wage along with our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary) and our adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr)	Adjusted hourly wage ($/hr)
Business Operations Specialists	13–1000	40.04	40.04	80.08
Chief Executives	11–1011	118.48	118.48	236.96
Computer Programmers	15–1251	49.42	49.42	98.84
Data Entry/Information Processing Workers	43–9020	18.97	18.97	37.94
General Operations Manager	11–1021	59.07	59.07	118.14
Statistician	15–2041	50.73	50.73	101.46

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

To estimate the burden on States, it was important to consider the Federal government's contribution to the cost of administering the Medicaid and CHIP programs. The Federal government provides Federal Medicaid funds for medical assistance based on an FMAP that is established for each State, based on the per capita income in the State as compared to the national average. FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capita incomes. States receive an ''enhanced'' FMAP for administering their CHIP programs, ranging from 65 to 85 percent. Medicaid funding for U.S. territories works a bit differently than funding for the 50 States and District of Columbia. Section 5101 of subtitle A of title V of division FF of the CAA, 2023 permanently set the FMAP for the four smaller territories (the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) under Medicaid at 83 percent. Puerto Rico's FMAP under Medicaid is statutorily set at 55 percent but has been temporarily increased to 76 percent until September 30, 2027.[58] For each territory, the annual amount of available Federal matching funds is capped. For Medicaid, all States (including the territories) receive a 50 percent Federal matching rate for activities found necessary by the Secretary for the proper and efficient administration of the Medicaid program. As noted previously in this final rule, States may receive higher Federal matching rates for expenditures on certain services and for certain systems improvements, redesign, or operations, up to 90 percent. As such, in considering the Federal contribution to the costs of administering the Medicaid and CHIP programs for purposes of estimating State burden with respect to collection of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs, even though the burden would likely be much smaller.

Beneficiaries: We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $21.98/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices [59] identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly

[57] The costs associated with our August 22, 2022, proposed rule differ from the costs in this final rule since the proposed rule used BLS' May 2020 mean hourly wages whereas this final rule uses BLS' 2022 wage estimates.

[58] See section 1905(ff) of the Act.

[59] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//176806/VOT.pdf.*

earnings of wage and salary workers of $1,059[60] for 2022, divided by 40 hours to calculate an hourly pre-tax wage rate of $26.48/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent or $4.50/hr ($26.48/hr × 0.17), resulting in the post-tax hourly wage rate of $21.98/hr.

Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Information Collection Requirements (ICRs)

The following collection of information requirements and burden estimates were posted for public review and submitted to OMB for review under control number 0938–1188 (CMS–10434 #26 for the Child Core Set and the Adult Core Set and CMS–10434 #47 for the Health Home Core Sets) in association with the August 22, 2022 proposed rule.

Under sections 1139A, 1139B, and 1902(a)(6) of the Act, we have the authority to collect quality metrics on State-specific Medicaid and CHIP programs for the purpose of: measuring the overall national quality of care for Medicaid and CHIP beneficiaries, monitoring performance at the State-level, and improving the quality of health care. Under sections 1902(a)(6), 1945(c)(4)(B), 1945(g), and 1945A(g) of the Act, in this final rule, we are requiring States that are implementing the section 1945 and/or section 1945A health home benefits to report on certain quality measures to the Secretary and to require their health home providers to report on these same measures to the State. The reported data is intended to provide a comprehensive landscape of the quality of care provided by Medicaid and CHIP, because the measures focus on a range of topics including access to primary and preventive care, maternal and perinatal health care, care of acute and chronic conditions, behavioral health care, dental and oral health care, long term services and supports, and overall experience of care.

Currently, Child, Adult, and section 1945 Health Home Core Sets reporting is voluntary for States but highly encouraged. Under this final rule, our voluntary annual reporting requirements will become mandatory for States for the: Child Core Set (CMS–10434 #26), behavioral health measures in the Adult Core Set (also CMS–10434 #26), and the section 1945 and forthcoming section 1945A Health Home Core Sets (CMS–10434 #47).[61] This final rule does not add, remove, or revise any of the existing measures in any of the aforementioned Core Sets. Annual updates to the Core Sets will continue to be made as required by sections 1139A and 1139B of the Act for the Child and Adult Core Sets and this annual update process will also be applied to both Health Home Core Sets as described in section I.C. of this preamble and §§ 437.10(a)(2) and (e). Mandatory reporting of the Child Core Set and behavioral health measures on the Adult Core Set will impact all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands as described in section II.A. of this final rule and in § 437.1. The Health Home Core Sets requirements will apply if a State (as defined under section 1101 of the Act for purposes of Title XIX) has an approved Health Home SPA under section 1945 or 1945A of the Act (see § 437.1(d)(2)), and the burden associated with the mandatory reporting requirement is not expected to influence the number of health home SPAs. Currently, 19 States and DC have a total of 34 section 1945 Health Home SPAs.

Under this final rule, we anticipate that the mandatory reporting burden for States would increase in comparison to the current voluntary Core Set reporting burden, including anticipated burden to States for system changes as a result of this final rule. This is due to the mandatory nature of the data collection which may increase: the number of measures reported by States, adherence to the reporting guidance provided by CMS, and stratification of data by delivery system and demographic characteristics. However, many of the mandatory measures can be calculated from alternate data sources. For example, we have been working to use T–MSIS (CMS–R–284, OMB 0938–0345) reporting to generate measure reporting on behalf of States. Among the three Core Sets, approximately 50 measures will become mandatory (the Child Core Set measures, behavioral health measures on the Adult Core Set, and the 1945 and 1945A Health Home Core Sets of measures for States with a health home program), two of which we currently report for States and Puerto Rico using alternate data sources. The remaining non-behavioral health Adult Core Set measures will remain voluntary for States to report. The burden to report voluntary measures is not included in this final rule but is submitted annually to OMB for their approval under control number 0938–1188 (CMS–10434 #26). We are currently assessing whether T–MSIS could be used to report any of the remaining measures. If so, this will reduce the number of measures that States will be required to calculate.

The data fields included in Core Set reporting templates are determined by the measure stewards who own the measures. We are not the measure steward for most measures, and therefore, do not control the actual data fields for most of the measures in the Core Sets. As a result, the templates used for Core Sets reporting will not be published for public comment. Instead, measure stewards implement a separate process for public comment during measure development and measurement updates. We also have recommendations in the CMS Measures Management System Blueprint for a similar process for public comment during measure development.[62]

We are adding SPA preprints to the final rule package under control number 0938–1188 (CMS–10434 #26) for the Child Core Set and the Adult Core Set and CMS–10434 #22, entitled: ''Health Home State Plan Amendment (SPA)'') for the Health Home Core Sets. These preprints were excluded from the proposed rule package, but the contents of the preprints were described under the collection of information requirements, and the burden estimates were included under ICR #1 in the proposed rule. The final rule's preprint does not deviate from those descriptions: ''that the agency would report on the Child and Adult Core Sets in accordance with the requirements in § 437.20(a)'' and that States would need ''to submit a SPA attesting that the agency would report on the Health Home Core Sets in accordance with the requirements in § 437.20(a).'' Additionally, we are changing the package under which the Health Home Core Sets SPA preprint is associated from control number 0938–1188 (CMS–10434 #47) to 0938–1188 (CMS–10434 #22, entitled: ''Health Home State Plan Amendment (SPA)''), as this package (CMS–10434 #22) is associated with the health home program State plan requirements. The requirements for the SPA are the same, and the burden set out in the proposed rule is the same as in the final rule (at 54 responses × 1

[60] *https://fred.stlouisfed.org/series/LEU0252881500A.*

[61] Core Set Measure lists: *https://www.medicaid.gov/medicaid/quality-of-care/index.html.*

[62] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.*

hour/response = 54 hours total time); only the location is being changed.

Subsequent to the proposed rule we have revised §§ 437.10(b)(5)(i) and 437.15(a)(4) and (6) in this final rule to allow States to request a 1-year exemption from Child and Adult Core Sets reporting for specific populations that have not already been exempted by the Secretary for the year in question in the annual subregulatory guidance. Our assessment of the burden of the exemption request process has been added under ICR #5 (54 responses × 4 hour/response = 216 hours total time). This option is available to all States, and the burden includes all States and Territories subject to mandatory reporting requirements for the Child and Adult Core Sets who may submit an exemption request. As required by the PRA, we will solicit public comment via 60-day and 30-day notices that we will issue in the **Federal Register** separate from this rulemaking document as this voluntary requirement takes effect September 1, 2024.

As noted previously in this rule, we received one public comment related to the collection of information requirements calculation of the burden estimate, which applied to the estimates provided for reporting the Child, Adult, and Health Home Core Sets. The comment, and our response can be found in section III.C. of this final rule.

The burden for reporting voluntary Adult Core Set measures (the measures outside of behavioral health measures) for States to report is not included in this rule's ICR discussions as the mandatory reporting requirements being implemented with this final rule do not apply to the voluntary measures; however, these costs will be included under control number 0938–1188 (CMS–10434 #26). The burden to health home providers for reporting section 1945 and section 1945A Health Home Core Sets data to States is not included in this rule's ICR discussions or under control number 0938–1188 (CMS–10434 #47) as this final rule outlines State requirements to comply with reporting the Health Home Core Sets. The burden to health home providers for reporting the section 1945 and section 1945A Health Home Core Sets along with the development of a Health Home SPA is approved by OMB under control number 0938–1188 (CMS–10434 #22, entitled: ''Health Home State Plan Amendment (SPA)'').

1. ICRs Regarding Attestation of Mandatory Reporting (§ 437.20(a))

The following changes will be submitted to OMB for their approval under control number 0938–1188 (CMS–10434 #26 and CMS–10434 #22). As noted previously in this final rule, we are changing the package under which the Health Home Core Sets SPA preprint is associated from control number 0938–1188 (CMS–10434 #47) to 0938–1188 (CMS–10434 #22, entitled: ''Health Home State Plan Amendment (SPA)'') as this package (CMS–10434 #22) is associated with the health home program State plan requirements.

With the changes outlined in this final rule, the 50 States, DC, Puerto Rico, Guam, and the Virgin Islands that will be subject to the Child and Adult Core Sets reporting requirements will need to submit a single SPA attesting that the agency will report on the Child and Adult Core Sets in accordance with the requirements in § 437.20(a). The approximately 20 States (with approximately 40 health home programs) with section 1945 Health Home SPAs and the approximately 10 States estimated to apply for section 1945A Health Home SPAs would need to submit a SPA attesting that the agency would report on the Health Home Core Sets in accordance with the requirements in § 437.20(a). Health Home SPAs will also include an attestation that the State will require its providers of health home services to report to the State on the measures that the State has to report in accordance with the requirements in § 437.20(a).

We estimate it would take a business operations specialist 2 hours at $80.08/hr and a general operations manager 1 hour at $118.14/hr to update and submit the State or territory SPA to us for review. We estimate a one-time burden of 162 hours (54 States and territories × 3 hr/response) at a cost of $15,028 (54 States and territories × ([2 hr/response × $80.08/hr] + [1 hr/response × $118.14/hr])). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $7,514 ($15,028 × 0.50). CMS is attributing ⅔ of this burden ($5,009 State share and 108 hr) to Child and Adult Core Sets reporting and ⅓ to Health Home Core Sets reporting ($2,505 State share and 54 hr). CMS is attributing additional burden to Child and Adult Core Sets reporting (versus Health Home Core Sets reporting) due to additional effort to coordinate attestation of State Core Sets reporting across State Medicaid and CHIP programs.

TABLE 2—ATTESTATION REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188

[CMS–10434 #26, Child Core Set and the Adult Core Set]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.20—One-time SPA Submission*	54	54	2	108 (162 hr × ⅔)	Varies	10,019	5,009

*States will be required to submit a SPA that attests that the State will be in compliance with Child, Adult, and Health Home Core Sets reporting. Every State would complete the SPA and States with a Health Home would only have to identify as applicable.

TABLE 3—ATTESTATION REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188

[CMS–10434 #22, Health Home SPA]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.20—One-time SPA Submission*	54	54	1	54 (162 hr × ⅓)	Varies	5,009	2,505

*States will be required to submit a SPA that attests that the State will be in compliance with Child, Adult, and Health Home Core Sets reporting. Every State would complete the SPA and States with a Health Home would only have to identify as applicable.

2. ICRs Regarding Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) (Part 437, Subpart A)

The following will be submitted to OMB for their approval under control number 0938–1188 (CMS–10434 #26).

As required by section 50102(b) of the Bipartisan Budget Act of 2018, a new subparagraph (B) was added to section 1139A(a)(4) of the Act to mandate annual reporting of the Child Core Set beginning with the annual State report on FFY 2024. As referenced in section II.A. of this final rule, mandatory reporting of the Child Core Set will be required for all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands. The data collection, as explained in section II.C. of this final rule, will be required to include: reporting on all mandatory measures following the reporting guidance provided by CMS; populations, identified by CMS, for which States must report on each measure such as specified delivery systems, health care settings, and beneficiaries dually eligible for Medicare and Medicaid; and the stratification of certain measures by factors such as race, ethnicity, sex, age, rural/urban status, disability and language.

The burden for each respondent is dependent on the State reporting structure and the status of the State's Medicaid and CHIP programs. Currently, there are 14 States and territories with Medicaid expansion CHIP only, 2 States with separate CHIPs, and 38 States with both Medicaid expansion and separate CHIPs.[63] We expect the burden for States with separate CHIPs or both types of CHIPs to be higher than for States with Medicaid expansion CHIP only. This is because States with separate CHIPs or both types of CHIPs would have to report data for children enrolled across both Medicaid and CHIP. This would result in more complex data sets and would require the State to conduct the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey twice, once for Medicaid and once for CHIP.[64] To account for the added reporting and survey effort for States with separate CHIP or with both Medicaid expansion and separate CHIPs, we have applied a multiplier of 1.5 to the burden hours for Child Core Set measure reporting and a multiplier of 2 to the burden estimate for conducting and reporting CAHPS survey data.

For the 14 States with Medicaid expansion CHIP only, we expect that the reporting of approximately 25 Child Core Set measures would take: 154 hours at $98.84/hr for a computer programmer to re-program and synthesize the data; 20 hours at $101.46/hr for a statistician to conduct data sampling; 115 hours at $118.14/hr for a general operations manager to analyze the data; 216.5 hours at $37.94/hr for a data entry worker to input the data; and 11.75 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to CMS.[65] We estimate an annual burden of 7,242 hours (517.25 hr × 14 responses) at a cost of $585,689 (14 responses × ([154 hr × $98.84/hr] + [20 hr × $101.46/hr] + [115 hr × $118.14/hr] + [216.5 hr × $37.94/hr] + [11.75 hr × $236.96/hr])).

Additionally, we expect the new reporting mandate to require vendor contract modifications in all 14 States. We expect the contract modifications would take 6 hours at $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/hr for a chief executive to review and approve a modified vendor contract. We estimate an annual burden of 112 hours (8 hr/response × 14 responses) at a cost of $16,559 (14 responses × ([6 hr × $118.14/hr] + [2 hr × $236.96/hr])).

In aggregate, for States with Medicaid expansion CHIP only, we estimate an annual State burden of 7,354 hours (7,242 hr + 112 hr) at a cost of $602,248 ($585,689 + $16,559). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $301,124 ($602,248 × 0.50).

For the 40 States (with separate CHIPs (2) and States with both Medicaid Expansion and separate CHIPs (38)) we expect a higher burden, because States with separate CHIP programs or combination CHIP programs would have to report data for children enrolled across both Medicaid and CHIP programs. We expect the Child Core Set of approximately 25 measures would take: 264.5 hours at $98.84/hr for a computer programmer to collect and synthesize the data; 40 hours at $101.46/hr for a statistician to conduct data sampling; 186.5 hours at $118.14/hr for a general operations manager to analyze the data; 427.75 hours at $37.94/hr for a data entry worker to input the data; and 18 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to CMS. We estimate an annual burden of 37,480 hours (937 hr × 40 responses) at a cost of $2,909,152 (40 responses × ([264.5 hr × $98.84/hr] + [40 hr × $101.46/hr] + [186.5 hr × $118.14/hr] + [427.75 hr × $37.94/hr] + [18 × $236.96/hr])).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/hr for a chief executive to review and approve a modified vendor contract. We estimate an annual burden of 320 hours (8 hr × 40 responses) at a cost of $47,310 (40 responses × ([6 hr × $118.14/hr] + [2 hr × $236.96/hr])).

In aggregate, for States with separate CHIPs and States with both Medicaid Expansion and separate CHIPs, we estimate an annual State burden of 37,800 hours (37,480 hr + 320 hr) at a cost of $2,956,462 ($2,909,152 + $47,310). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $1,478,231 ($2,956,462 × 0.50).

The CAHPS measure is the only mandatory measure on the Child Core Set which would include a burden on beneficiaries. We estimate it would take 20 minutes (0.33 hr) at $21.98/hr for a Medicaid or CHIP beneficiary to complete the CAHPS Health Plan Survey (Child Core Set includes: Child version including Medicaid and Children with Chronic Conditions Supplemental Items). The collected survey data are incorporated into a Child Core Set measure.

For the 14 States with Medicaid expansion CHIP programs only, the survey will be conducted once each year. We estimate an annual per State beneficiary burden of 136 hours (0.33 hr per response × 411 beneficiary responses/State × 1 survey/yr) at a cost of $2,989 (136 hr × $21.98/hr).[66] In aggregate, for States with Medicaid expansion CHIP only, we estimate an annual beneficiary burden of 1,904 hours (136 hr × 14 States) at a cost of $41,846 ($2,989 × 14 States). We estimate a total of 5,754 beneficiary

[63] *https://www.medicaid.gov/chip/downloads/chip-map.pdf.*

[64] The Agency for Healthcare Research and Quality is the measure steward for the CAHPS survey (CAHPS health plan database OMB Control No.: 0935–0165).

[65] Child Core Set: *https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/childrens-health-care-quality-measures/index.html.*

[66] Per CAHPS Health Plan Survey 5.1H Guidelines: The sample needs to be large enough to achieve a goal of 411 completed surveys per reporting unit (for example, health plan or State).

responses (14 States × 411 beneficiary responses).

States with combination CHIP programs or separate CHIP program only would conduct the survey twice each year to account for the separate Medicaid and CHIP populations. There are 40 States and territories with this program structure. We estimate an annual per State beneficiary burden of 271 hours (0.33 hr per response × 411 beneficiary responses/State × 2 surveys/yr) at a cost of $5,957 (271 hr × $21.98/hr).[67] In aggregate, for States with combination CHIP programs or separate CHIP program only, we estimate an annual beneficiary burden of 10,840 hours (271 hr × 40 States) at a cost of $238,280 ($5,957 × 40 States). We estimate a total of 32,880 beneficiary responses (40 States × 411 beneficiary responses × 2 surveys/year).

For States to administer the survey, we estimate an ongoing aggregate beneficiary burden of 12,744 hours (1,904 + 10,840 hr) at a cost of $280,126 ($41,846 + $238,280).

TABLE 4—CHILD CORE SET REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188
(CMS–10434 #26, Child Core Set and the Adult Core Set)

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15—Medicaid Expansion CHIP Programs	14	14	525.25	7,354	Varies	602,248	301,124
§ 437.15—States with combination CHIP programs or separate CHIP programs only.	40	40	945	37,800	Varies	2,956,462	1,478,231
Subtotal: States	54	54	Varies	45,154	Varies	3,558,710	1,779,355
§ 437.15—CAHPS survey: Medicaid Expansion CHIP Programs.	5,754	5,754	0.33	1,904	21.98	41,846	NA
§ 437.15—CAHPS survey: States with combination CHIP programs or separate CHIP programs only.	32,880	32,880	0.33	10,840	21.98	238,280	NA
Subtotal: CAHPS Survey beneficiary	38,634	38,634	Varies	12,744	21.98	280,126	NA
Total	38,688	38,688	Varies	57,898	Varies	3,838,836	1,779,355

3. ICRs Regarding Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set) (Part 437, Subpart A)

The following changes will be submitted to OMB for their approval under control number 0938–1188 (CMS–10434 #26).

As required by the SUPPORT Act, a new subparagraph (b)(3)(B) was added to section 1139B of the Act, to make mandatory the annual reporting of behavioral health measures in the Adult Core Set beginning with the annual State report on FFY 2024. As referenced in section II.A. of this final rule, mandatory reporting of the Adult Core Set will be required for all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands. The data collection, as explained in section II.C. of this final rule, is required to include: reporting on all mandatory measures following the reporting guidance provided by CMS; populations, identified by CMS, for which States must report on each measure such as specified delivery systems, health care settings, and beneficiaries dually eligible for Medicare and Medicaid; and the stratification of certain measures by factors such as race, ethnicity, sex, age, rural/urban status, disability and language.

For the behavioral health measures on the Adult Core Set, consisting of approximately 13 measures, we estimate it would take: 115 hours at $98.84/hr for a computer programmer to re-program and synthesize the data; 20 hours at $101.46/hr for a statistician to conduct data sampling; 76 hours at $118.14/hr for a general operations manager to analyze the data; 212 hours at $37.94/hr for a data entry worker to input the data; and 6.5 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to CMS.[68] We estimate an annual burden of 23,193 hours (429.5 hr/response × 54 responses) at a cost of $1,725,730 (54 responses × ([115 hr × $98.84/hr] + [20 hr × $101.46/hr] + [76 hr × $118.14/hr] + [212 hr × $37.94/hr] + [6.5 × $236.96/hr])).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/hr for a chief executive to review and approve a modified vendor contract. We estimate a one-time burden of 432 hours (8 hr × 54 responses) at a cost of $63,869 (54 responses × ([6 hr × $118.14/hr) + [2 hr × $236.96/hr])).

In aggregate, we estimate an annual State burden of 23,625 hours (23,193 hr + 432 hr) at a cost of $1,789,599 ($1,725,730 + $63,869). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $894,800 ($1,789,599 × 0.50).

The CAHPS measure is the only mandatory measure on the Adult Core Set which would include a burden on beneficiaries.[69] We estimate it would take 20 minutes (0.33 hr) at $21.98/hr for a Medicaid beneficiary to complete a CAHPS Health Plan survey. The collected survey data is incorporated into one of the behavioral health measures on the Adult Core Set. For each State Medicaid program, we estimate an annual per State beneficiary burden of 136 hours (0.33 hr/response × 411 beneficiary responses/State) at a cost of $2,989 (136 hr × $21.98/hr).[70] For States to administer the survey, in aggregate, we estimate an annual beneficiary burden of 7,344 hours (136 hr/State × 54 States) at a cost of $161,406 ($2,989 per State × 54 States). We estimate a total of 22,194 beneficiary

[67] Per CAHPS Health Plan Survey 5.1H Guidelines: The sample needs to be large enough to achieve a goal of 411 completed surveys per reporting unit (for example, health plan or State).

[68] *https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-health-care-quality-measures/index.html.*

[69] The Agency for Healthcare Research and Quality is the measure steward for the CAHPS survey (CAHPS health plan database OMB Control No.: 0935–0165).

[70] Per CAHPS Health Plan Survey 5.1H Guidelines: The sample needs to be large enough to achieve a goal of 411 completed surveys per reporting unit (for example, health plan or State).

responses (54 States × 411 beneficiary responses).

TABLE 5—ADULT CORE SET REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188

[CMS–10434 #26, Child Core Set and the Adult Core Set]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15—(Adult Core Set) States	54 States	54	437.5	23,625	Varies	1,789,599	894,800
§ 437.15—CAHPS Survey (Beneficiaries)	22,194	22,194	0.33	7,344	21.98	161,406	NA
Total	22,248	22,248	Varies	30,969	Varies	1,951,005	894,800

4. ICRs Regarding Core Sets of Health Home Quality Measures for Medicaid (Health Home Core Sets) (Part 437, Subpart A)

The following changes will be submitted to OMB for their approval under control number 0938–1188 (CMS–10434 #47). The burden associated with health home providers submitting data to the States is not included in this ICR as the burden estimate for the 1945 and 1945A health home programs is already included in control number 0938–1188 (CMS–10434 # 22). Including the provider burden in this estimate would be duplicative.

Sections 1945(g) and 1945A(g)(1)(B) of the Act require health home providers to report to States on measures for determining the quality of health home services provided, as a condition for payment of such services. Sections 1945(c)(4)(B) and 1945A(g)(2) of the Act require States to report on certain health home information to the Secretary, and we rely on these authorities, as well as on section 1902(a)(6) of the Act, in proposing to require all States implementing the section 1945 or section 1945A health home benefits to report on mandatory measures in the Health Home Core Sets. Additionally, to enable this State reporting, States will be required to require their health home providers to report on these measures too, consistent with sections 1945(g) and 1945A(g)(1)(B) of the Act. As discussed in section II.A. of this final rule, State reporting of the Health Home Core Sets would be required only if the State (as defined in section 1101 for purposes of Title XIX) has an approved health home SPA under sections 1945 or 1945A of the Act. The data collection, as explained in section II.C. of this final rule, will be required to include: reporting on all mandatory measures following the reporting guidance provided by CMS; all beneficiaries served in each State's relevant health home program; and the stratification of data under certain measures by factors such as race, ethnicity, sex, age, rural/urban status, disability and language.

The burden for each respondent is dependent on the State's adoption of Health Home programs. We expect approximately 20 States to operate approximately 40 Health Home programs under section 1945 authority and approximately 10 States to operate Health Home programs under section 1945A authority.

Section 1945 Authority: The section 1945 Health Home Core Set for section 1945 programs consists of approximately 13 measures. For each respondent with this program, we estimate it would take: 52 hours at $98.84/hr for a computer programmer to collect and synthesize the data; 52 hours at $118.14/hr for a general operations manager to analyze the data; 6.5 hours at $37.94/hr for a data entry worker to input the data; and 6.5 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to CMS. We estimate an annual burden of 4,680 hours (117 hr × 40 responses) at a cost of $522,792 (40 responses × ([52 hr × $98.84/hr] + [52 hr × $118.14/hr] + [6.5 hr × $37.94/hr] + [6.5 × $236.96/hr])).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/hr for a chief executive to review and approve a modified vendor contract. We estimate a one-time burden of 320 hours (8 hr × 40 responses) at a cost of $47,310 (40 responses × ([6 hr × $118.14/hr) + [2 hr × $236.96/hr])).

In aggregate, for States with a 1945 health home program, we estimate an annual burden of 5,000 hours (4,680 hr + 320 hr) at a cost of $570,103 ($522,792 + $47,310). Taking into account the Federal contribution to Medicaid program administration, the estimated State share of this cost is approximately $285,052 ($570,103 × 0.50).

Note that the section 1945 Health Home Core Set does not include a survey-based measure; thus, there are no burden and cost estimates associated with a survey, such as the costs of a statistician to conduct sampling and weighting for the survey.

TABLE 6—1945 ADULT CORE SET REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188

[CMS–10434 #47, Health Home Core Sets]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15—(1945 Health Home Core Set)	40	40	125	5,000	Varies	570,103	285,052

Section 1945A Authority: We anticipate that the section 1945A Health Home Core Set for section 1945A programs would consist of approximately 7 measures. For each respondent with this program, we estimate it would take: 28 hours at $98.84/hr for a computer programmer to collect and synthesize the data; 28 hours at $118.14/hr for a general operations manager to analyze the data; 3 hours at $37.94/hr for a data entry worker to

input the data; and 3 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to us. We estimate an annual State burden of 620 hours (62 hr/response × 10 responses) at a cost of $69,001 (10 responses × ([28 hr × $98.84/hr] + [28 hr × $118.14/hr] + [3 hr × $37.94/hr] + [3 × $236.96/hr])).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/hr for a chief executive to review and approve a modified vendor contract. We estimate a one-time burden of 80 hours (8 hr × 10 responses) at a cost of $11,828 (10 responses × ([6 hr × $118.14/hr) + [2 hr × $236.96/hr])).

In aggregate, for States with a 1945A health home program, we estimate an annual State burden of 700 hours (620 hr + 80 hr) at a cost of $80,829 ($69,001 + $11,828). Taking into account the Federal contribution to Medicaid program administration, the estimated State share of this cost is approximately $40,415 ($80,829 × 0.50).

Note that we anticipate that the section 1945A Health Home Core Set would not include a survey-based measure; thus, there are no burden and cost estimates associated with a survey, such as the costs of a statistician to conduct sampling and weighting for the survey.

TABLE 7—1945A ADULT CORE SET REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188

[CMS–10434 #47, Health Home Core Sets]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15—(1945A Health Home Core Set)	10	10	70	700	Varies	80,829	40,415

5. ICRs Regarding Optional Request for Exemption From Mandatory Child and Adult Core Sets Reporting for Specific Populations (Child and Adult Core Sets (Part 437, Subpart A))

With the changes outlined in this final rule, the 50 States, DC, Puerto Rico, Guam, and the Virgin Islands that will be subject to the Child and Adult Core Sets reporting requirements will have an opportunity each year to request a 1-year exemption from reporting data for one or more mandatory populations for the Child and Adult Core Sets if the State demonstrates an inability to obtain access to data required to report on the Child and Adult Core Sets in accordance with the requirements in §§ 437.10(b)(5), 437.15(a)(4)(ii), and (6). We have added this option to address concerns about the feasibility of Child and Adult Core Sets reporting for specific populations. A State that needs an exemption must request the exemption from CMS by September 1st of the applicable reporting year, the exemption would be only for that year's reporting, and it would apply only to the specific population for which the State receives an exemption for reporting that population in one or more measures. The State would be required to define the specific population for which exemption from reporting is sought and to which measure(s) the request applies. The State will be required to explain why this exemption is necessary (that is, why the State agency was not able to obtain access to the data required to report on the relevant population) and what actions are underway to resolve the data access problems. In addition, the State must demonstrate to us that it has made a reasonable effort to obtain the required data by the reporting deadline. As discussed previously in this final rule, we will solicit public comment via 60-day and 30-day Paperwork Reduction Act notices that we will issue in the **Federal Register** separate from this rulemaking document before this voluntary requirement takes effect September 1, 2024.

The process to request an exemption from reporting one or more mandatory populations for the Child and Adult Core Sets will require the state to submit an exemption request to us. We estimate it would take a business operations specialist 1 hour at $80.08/hr to determine which populations the state is unable to report, a general operation manager 2 hours at $118.14/hr to draft an exemption request and 1 hour at $236.96/hr for a chief executive to review, approve, and submit the exemption request. We estimate an annual burden of 216 hours (54 States and territories × 4 hr/response) at a cost of $29,879 (54 States and territories × ([1 hr/response × $80.08/hr] + [2 hr/response × $118.14/hr]) + [1 hr/response × $236.96/hr])). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $14,940 ($29,879 × 0.50).

TABLE 8—REQUEST FOR EXEMPTION FROM REPORTING SPECIFIC POPULATIONS

[Child/Adult Core Sets only]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15(a)(6)—Annual Exemption Request*	54	54	4	216 hrs	Varies	29,879	14,940

*States will have the option to submit a request for exemption from reporting one or more mandatory populations. Exemption requests only apply to Child and Adult Core Sets reporting.

C. Summary of Annual Requirements and Annual Burden Estimates

As stated in section II. of this final rule, we received 93 public comments on the proposed rule, but only one of those comments was related to the rule's collection of information requirements.

Comment: One commenter noted that in their experience with the Child and Adult Core Sets, the time to convert the reporting guidance into analytic code is underestimated in the COI (by 3–4 times) and the time to input the data is an overestimate.

Response: As the COI estimate reflects the average costs for all States that are required to comply with mandatory Core Set reporting requirements, it is expected that there will be variation in time estimates experienced by individual States. Upon additional review, we have revised the COI estimate for the Child and Adult Core Sets to reflect the issue raised by this public comment and added additional time to program, synthesize, analyze, and review the data. We are working with States to develop strategies to reduce the burden of implementing reporting guidance and for FFY 2021 reporting introduced a new reporting system to help reduce the burden of Core Set reporting. We will continue to work with States to identify best practices and strategies to further reduce this burden and incorporate this information into reporting guidance and technical assistance materials.

Table 9 sets out our annual burden estimates.

TABLE 9—SUMMARY OF ANNUAL REQUIREMENTS AND BURDEN

[OMB Control Number: 0938–1188]

Section 437 under Title 42 of the CFR	Number of respondents	Total responses	Time per response (hours)	Total time (hours)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
CMS–10434 #26							
§ 437.20—One-time SPA Submission*	54	54	2	108	Varies	10,019	5,009
§ 437.15—Medicaid Expansion CHIP Programs	14	14	525.25	7,354	Varies	602,248	301,124
§ 437.15—CAHPS survey: Medicaid Expansion CHIP Programs.	5,754	5,754	0.33	1,904	21.98	41,846	NA
§ 437.15—States with combination CHIP programs or separate CHIP programs only.	40	40	945	37,800	Varies	2,956,462	1,478,231
§ 437.15—CAHPS survey: States with combination CHIP programs or separate CHIP programs only.	32,880	32,880	0.33	10,840	21.98	238,280	NA
§ 437.15—(Adult Core Set)	54	54	437.5	23,625	Varies	1,789,599	894,800
§ 437.15—CAHPS: (Adult Core Set)	22,194	22,194	0.33	7,344	21.98	161,406	NA
Subtotal (#26)		60,990	Varies	88,975	Varies	5,799,860	2,679,164
CMS–10434 #22							
§ 437.20—One-time SPA Submission*	54	54	1	54	Varies	5,009	2,505
Subtotal (#22)	54	54	1	54	Varies	5,009	2,505
CMS–10434 #47							
§ 437.15—(1945 Health Home Core Set)	40	40	125	5,000	Varies	570,103	285,052
§ 437.15—(1945A Health Home Core Set)	10	10	70	700	Varies	80,829	40,415
Subtotal (#47)	50	50	Varies	5,700	Varies	650,932	325,467
CMS–10867							
§ 437.15(a)(6)—Annual Exemption Request*	54	54	4	216	Varies	29,879	14,940
Total	Varies	61,148	Varies	94,945	Varies	6,485,680	3,022,076

*States will be required to submit a SPA that attests that the State will be in compliance with Child, Adult, and Health Home Core Sets reporting. Every State would complete the SPA and States with a Health Home would only have to identify as applicable.

IV. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 as amended by Executive Order 14094 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles set forth in the Executive Order. OIRA has determined that this final rule is significant, and it was accordingly reviewed by OMB.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and States are not included in the definition

of a small entity. This final rule applies to new mandatory reporting requirements for information collection from State Medicaid and CHIP agencies who do not meet the definition of a small business. Therefore, we are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule would not have a significant economic impact on any small entities. In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. This proposed rule applies to State Medicaid and CHIP agencies and would not add requirements to rural hospitals or other small providers. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule would not have a significant impact on the operations of small rural hospitals. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This rule would have no consequential effect on State, local, or tribal governments or on the private sector. Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this regulation does not impose any substantial direct compliance costs on State or local governments, preempt State law, or otherwise have federalism implications, the requirements of Executive Order 13132 are not applicable. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on August 23, 2023.

List of Subjects

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 437

Administrative practice and procedure, Claims, Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 433—STATE FISCAL ADMINISTRATION

■ 1. The authority citation for part 433 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Amend § 433.112 by revising paragraph (b)(12) to read as follows:

§ 433.112 FFP for design, development, installation or enhancement of mechanized processing and information retrieval systems.

* * * * *

(b) * * *

(12) The agency ensures alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B. The agency also ensures alignment with: the HIPAA privacy, security, breach notification and enforcement regulations in 45 CFR parts 160 and 164; and the transaction standards and operating rules adopted by the Secretary under HIPAA and/or section 1104 of the Affordable Care Act. The agency meets accessibility standards established under section 508 of the Rehabilitation Act, or standards that provide greater accessibility for individuals with disabilities, and compliance with Federal civil rights laws; standards and protocols adopted by the Secretary under section 1561 of the Affordable Care Act; standards and protocols for reporting on the Child and Adult Core Sets as adopted by the Secretary under sections 1139A, 1139B, and 1902(a)(6) of the Act, and 42 CFR part 437 subpart A; and standards and protocols for reporting on the Health Home Core Sets as adopted by the Secretary under sections 1902(a)(6), 1945(c)(4)(B) and (g), and 1945A(g) of the Act and 42 CFR part 437 subpart A.

* * * * *

■ 3. Part 437 is added to read as follows:

PART 437—MEDICAID QUALITY

Subpart A—Child, Adult, and Health Home Health Care Quality Measures

Subpart B [Reserved]

Authority: 42 U.S.C. 1320b–9a, 42 U.S.C. 1320b–9b, 42 U.S.C. 1396a(a)(6), 42 U.S.C. 1396w–4, and 42 U.S.C. 1396w–4a.

Subpart A—Child, Adult, and Health Home Health Care Quality Measures

§ 437.1 Basis, scope, purpose, and applicability.

(a) *Statutory basis.* This subpart is based on sections 1139A, 1139B, 1902(a)(6), 1945(c)(4)(B), 1945(g), and 1945A(g) of the Act.

(b) *Scope.* This subpart sets forth specifications for issuance and updates to the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set), the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), and the 1945 and 1945A Core Sets of Health Home Quality Measures for Medicaid (Health Home Core Sets) by the Secretary. It also sets forth requirements related to annual reporting by States of measures in all of the Core Sets, and requirements related to provider reporting to States on the Health Home Core Sets.

(c) *Purpose.* (1) The purpose of the Medicaid and CHIP Child Core Set and the Medicaid Adult Core Set is to measure the overall national quality of care for beneficiaries, monitor performance at the State-level, and improve the quality of health care.

(2) The purpose of the Health Home Core Sets is to measure the overall program quality of health home services for Medicaid beneficiaries enrolled in a health home program under section 1945 or 1945A of the Act, monitor the impact of these two optional State plan benefits, monitor performance of these two benefits at the program level, and improve the quality of health care.

(d) *Applicability.* The provisions of this subpart apply as follows:

(1) For the Child and Adult Core Sets, State includes the 50 States, the District

of Columbia, Puerto Rico, the Virgin Islands, and Guam.

(2) For the Health Home Core Sets, State includes any State (as defined under section 1101 of the Act for purposes of Title XIX of the Act) with an approved Medicaid Health Home State Plan Amendment under section 1945 or 1945A of the Act.

(e) *Applicability dates.* States must comply with the requirements of this subpart by no later than State reporting on the 2024 Core Sets, which must be submitted and certified by December 31, 2024.

§ 437.5 Definitions.

As used in this subpart—

1945 Health Home Core Set means the Core Set of Health Home Quality Measures related to the Medicaid health home benefit under section 1945 of the Act, established and updated annually as described in § 437.10(a).

1945A Health Home Core Set means the Core Set of Health Home Quality Measures related to the Medicaid health home benefit under section 1945A of the Act, established and updated annually as described in § 437.10(a).

Adult Core Set means the Core Set of Adult Health Care Quality Measures for Medicaid established and updated annually as described in § 437.10(a).

Attribution rules means the process Medicaid and CHIP and other payers use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures on the Core Sets.

Behavioral health means a beneficiary's whole emotional and mental well-being, which includes, but is not limited to, the prevention, treatment, and recovery of mental disorders including substance use disorders.

Behavioral health measure means a quality measure that could be used to evaluate the quality of and improve the health care provided to beneficiaries with, or at-risk for a behavioral health disorder(s).

Child Core Set means the Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, established and updated annually as described in § 437.10(a).

Core Sets means the Child Core Set, the Adult Core Set, the section 1945 Health Home Core Set, and the section 1945A Health Home Core Set, collectively.

Health Home Core Sets means, collectively, the two Core Sets of Health Home Quality Measures related to the two Medicaid health home benefits under sections 1945 and 1945A of the Act, established and updated annually as described in § 437.10(a).

Standardized format means the format provided by the reporting system that States are required to utilize to submit Core Sets data to CMS.

§ 437.10 Child, Adult, and Health Home Core Sets.

(a) The Secretary shall—

(1) Identify, and annually update, the quality measures to be included in the Child, Adult, and Health Home Core Sets; and update the Child and Adult Core Sets beginning no later than January 1, 2024 and annually no later than January 1 thereafter.

(2) Consult annually with States and other interested parties identified in paragraph (e) of this section to—

(i) Establish priorities for the development and advancement of the Core Sets;

(ii) Identify any gaps in the measures included in the Core Sets;

(iii) Identify measures which should be removed as they no longer strengthen the Core Sets; and

(iv) Ensure that all measures included in the Core Sets reflect an evidence-based process including testing, validation, and consensus among interested parties; are meaningful for States; and are feasible for State-level and/or Health Home program level reporting, as appropriate.

(3) In consultation with States, develop and update annually the reporting guidance described in paragraph (b) of this section.

(4) Not later than September 30, 2025 and annually by September 30 thereafter, collect, analyze, and make publicly available the information reported by States on the Child and Adult Core Sets as described in § 437.15.

(5) Annually, collect, analyze, and make publicly available the information reported by States on the Health Home Core Sets as described in § 437.15.

(b) Annual reporting guidance will include all of the following:

(1) Identification of all measures in all the Core Sets, including:

(i) Measures newly added and measures removed from the prior year's Core Sets;

(ii) Measures included in the Adult Core Set that are identified as behavioral health measures;

(iii) The specific measures for which reporting is mandatory for the Child, Adult, and 1945 and 1945A Health Home Core Sets;

(iv) The measures for which the Secretary will complete reporting on behalf of States and the measures for which States may elect to have the Secretary report on their behalf; and

(v) The frequency of reporting for survey-based measures, which will be no more frequent than annually.

(2) Guidance to States on how to collect and calculate the data on the Core Sets.

(3) Standardized format for reporting measure data required under this subpart.

(4) Procedures that State agencies must follow in reporting measure data required under this subpart.

(5) Identification of the populations for which States may, but are not required to, report the Child and Adult Core Set measures identified by the Secretary under paragraph (b)(1) of this section for a specific year in accordance with paragraph (c) of this section.

(i) Additionally, CMS will include guidance to States on how to request a 1-year exemption from reporting one or more Child and/or Adult Core Set measures for specific populations in accordance with § 437.15(a)(4)(ii) and (6) of this part.

(ii) [Reserved]

(6) Attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population, during the reporting period.

(7) The subset of measures within the measures in the Child Core Set, among the behavioral health measures in the Adult Core Set, and among the measures in the Health Home Core Sets that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by annual consultation with States and interested parties in accordance with paragraphs (a)(2) and (d) of this section.

(c) In issuing the guidance described in paragraph (b) of this section, the Secretary may provide that Child and Adult Core Sets reporting for certain populations of beneficiaries described in paragraph (b)(5) of this section will be voluntary for a specific year, considering the level of difficulty in accessing the data required for such Child and Adult Core Sets State reporting.

(d) In specifying which measures, and by which factors, States must report stratified measures consistent with paragraph (b)(7) of this section, the Secretary will consider whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate; the Secretary

will require stratification of 25 percent of the measures on each of the Core Sets (the Child Core Set, behavioral health measures within the Adult Core Set, and Health Home Core Sets) for which the Secretary has specified that reporting should be stratified by the second year of annual reporting after the effective date of these regulations, 50 percent of such measures for the third and fourth years of annual reporting after the effective date of these regulations, and 100 percent of measures beginning in the fifth year of annual reporting after the effective date of these regulations.

(e) For purposes of paragraph (a)(2) of this section, the Secretary must consult with interested parties as described in this paragraph to include the following:

(1) States;

(2) Pediatricians, children's hospitals, and other primary and specialized pediatric health care professionals (including members of the allied health professions) who specialize in the care and treatment of children and adolescents, particularly children with special physical, mental, and developmental health care needs;

(3) Dental professionals, including pediatric dental professionals;

(4) Health care providers that furnish primary health care to children and families who live in urban and rural medically underserved communities or who are members of distinct population sub-groups at heightened risk for poor health outcomes;

(5) National organizations representing children and/or adolescents, including children with disabilities and children with chronic conditions;

(6) National organizations representing consumers and purchasers of children's health care;

(7) National organizations and individuals with expertise in pediatric health quality measurement;

(8) Voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care;

(9) With respect only to guidance on the Health Home Core Sets, providers of health home services under sections 1945 and 1945A of the Act;

(10) Such other interested parties as the Secretary may determine appropriate.

§ 437.15 Annual reporting on the Child, Adult, and Health Home Core Sets.

(a) *General rules.* (1) Except as provided in paragraphs (a)(2) and (a)(4) of this section, the agency—

(i) Must report by December 31, 2024, on all measures on the 2024 Child Core Set and the behavioral health measures in the Adult Core Set;

(ii) In subsequent years, must report annually, by December 31st, on all measures on the Child Core Set and the behavioral health measures in the Adult Core Set that are identified by the Secretary pursuant to § 437.10(b)(1)(iii);

(iii) Must report annually, by December 31st, on all measures in the 1945 or 1945A Health Home Core Sets (as applicable) that are identified by the Secretary pursuant to § 437.10(b)(1)(iii), if the agency has elected to offer health home services under the State plan under section 1945 or section 1945A of the Act, and if the applicable health home program has an effective date and has been implemented more than 6 months prior to the December 31st reporting deadline; and

(iv) May report on all other measures in the Adult Core Set that are not described in paragraphs (a)(1)(i) and (ii) of this section.

(2) Measures identified per § 437.10(b)(1)(iv) will be reported by the Secretary on behalf of the agency.

(3) The agency must adhere to the reporting guidance described in § 437.10(b), except as described in paragraph (a)(4) of this section, when reporting on measures in the Core Sets.

(4) In reporting on all Child and Adult Core Set measures, the agency is required to report on all Medicaid and CHIP beneficiaries, including those enrolled in fee-for-service and managed care, unless—

(i) The Secretary specifies in annual guidance that the population is not required to be reported in accordance with § 437.10(b)(5); or

(ii) The Secretary grants the agency an exemption from reporting one or more Child and Adult Core Set measures for a specific population in accordance with paragraph (a)(6) of this section.

(5) In reporting on all 1945 and 1945A Health Home Core Sets measures, the agency is required to report on all beneficiaries enrolled in an approved health home program.

(6)(i) The agency may request a 1-year exemption from reporting for a specific population defined by the State for one or more Child and/or Adult Core Set measures if the agency demonstrates that it:

(A) Is unable to obtain access to data required to report the relevant Child and Adult Core Set measure or measures for that population despite making reasonable efforts to do so; and

(B) Has a reasonable timeline of actions underway to resolve data access problems.

(ii) The agency must submit a request for an exemption by September 1st of the applicable reporting year.

(iii) If the Secretary determines that the agency satisfies the conditions set forth in paragraph (6)(i) of this section, the Secretary will approve the exemption only for that year's Child and/or Adult Core Set reporting and the exemption will apply only for the specific population for which the State requests an exemption. If the Secretary determines that the agency does not satisfy the conditions set forth in paragraph (a)(6)(i) of this section, the Secretary will communicate a denial of the exemption request to the agency, and the agency will be expected to include the relevant population in that year's Child and Adult Core Sets reporting.

(iv) The agency may request an exemption to reporting Child and Adult Core Set measures for the same population in accordance with this paragraph in more than one reporting year.

(b) *Reporting of Medicaid and CHIP beneficiaries.* In States that have implemented a separate child health program (''separate CHIP'') under part 457 of this chapter:

(1) The agency must report, in accordance with attribution rules established by the Secretary pursuant to § 437.10(b)(6), on measures included in the Child Core Set for—

(i) The Medicaid beneficiaries (including those for whom the State claims Federal financial participation under both Title XIX and Title XXI) in the age range to which the measure applies, as per reporting guidance described in paragraph § 437.10(b)(2); and

(ii) The beneficiaries in the State's separate CHIP in the age range to which the measure applies, as per reporting guidance described in paragraph § 437.10(b)(2).

(2) If the separate CHIP elects to report on Adult Core Set measures for individuals enrolled in their separate CHIP, the agency must report on individuals described in paragraphs (b)(1)(i) and (ii) of this section.

§ 437.20 State plan requirements.

(a) The State plan must specify that:

(1) The agency will report on the Child and Adult Core Sets in accordance with § 437.15.

(2) If health home services are covered under the State plan pursuant to section 1945 or 1945A of the Act, the agency will report on the applicable Health Home Core Set or Sets in accordance with § 437.15 of this subpart.

(3) If health home services are covered under the State plan pursuant to section 1945 or 1945A of the Act, the agency requires health home services providers to report to the agency on all populations served by the health home providers and on the measures in the applicable Health Home Core Set or Sets that are identified by the Secretary pursuant to § 437.10(b)(1)(iii), as a condition for receiving payment for health home services.

(b) [Reserved]

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 4. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 5. Amend § 457.700 by
■ a. In paragraph (a)(2) removing the word ''and'' at the end of the paragraph;
■ b. In paragraph (a)(3) by removing the period at the end of the paragraph and replacing it with ''; and''; and
■ c. Adding paragraph (a)(4).

The addition reads as follows:

§ 457.700 Basis, scope, and applicability.

* * * * *

(a) * * *

(4) Section 1139A and 1139B of the Act, which set forth the requirements for child and adult health quality measures and reporting.

* * * * *

■ 6. Add § 457.770 to read as follows:

§ 457.770 Reporting on Health Care Quality Measures.

(a) *Reporting the Child Core Set.* The State must report on the Core Set of Health Care Quality Measures for Children in Medicaid and CHIP (Child Core Set) for a separate child health program in accordance with part 437 of this chapter.

(b) *Reporting the Adult Core Set.* The State may elect to report on the Core Set of Adult Health Care Quality Measures in Medicaid (Adult Core Set) established by the Secretary in accordance with part 437 of this chapter. If the State reports measures on the Adult Core Set, such reporting must be in accordance with part 437 of this chapter, except that reporting on behavioral health measures on the Adult Core Set is not mandatory.

(c) *Reporting of Medicaid and CHIP beneficiaries.* The State must report measures included in the Child Core Set and, if applicable, Adult Core Set for individuals enrolled in a separate CHIP separately from individuals enrolled in Medicaid in accordance with § 437.15(b) of this chapter, regardless of whether the State claims Federal financial participation for such Medicaid-enrolled individuals under title XIX or title XXI of the Act.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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LIST OF PUBLIC LAWS

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