FEDERAL REGISTER

Vol. 88 Wednesday,

No. 215 November 8, 2023

Pages 76989–77194

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 88 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–09512—1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Contents

Federal Register

Vol. 88, No. 215

Wednesday, November 8, 2023

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 88, No. 215
Wednesday, November 8, 2023

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[NRC–2023–0187]

Regulatory Guide: Fire Protection for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 5 to Regulatory Guide (RG) 1.189, ''Fire Protection for Nuclear Power Plants.'' It is being issued to correct typographic errors that appeared in RG 1.189, Revision 4 of the same name. In addition, Revision 5 contains edits to conform with the current template for RGs and fixes to a few reference numbering errors. The changes in Revision 5 are intended to improve clarity and do not substantially alter the staff's regulatory guidance.

DATES: Revision 5 to RG 1.189 is available on November 8, 2023.

ADDRESSES: Please refer to Docket ID NRC–2023–0187 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0187. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individuals listed in the ''**FOR FURTHER INFORMATION CONTACT**'' section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

Revision 5 to RG 1.189 and the regulatory analysis may be found in ADAMS under Accession Nos. ML23214A287 and ML23214A295, respectively.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Charles Moulton, Office of Nuclear Reactor Regulation, telephone: 301–415–2751; email: *Charles.Moulton@nrc.gov* and Michael Eudy, Office of Nuclear Regulatory Research, telephone: 301–415–3104; email: *Michael.Eudy@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision in the NRC's ''Regulatory Guide'' series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

The NRC typically seeks public comment on a draft version of a RG by announcing its availability for comment in the **Federal Register**. However, as explained in NRC's Management Directive (MD) 6.6 ''Regulatory Guides,'' (ADAMS Accession No. ML22010A233) the NRC may directly issue a final RG without a draft version or public comment period if the changes to the RG are non-substantive. In addition, the NRC considers Revision 5 of RG 1.189 as an Administratively Changed Guide per MD 6.6.

II. Additional Information

The NRC issued Revision 4 of RG 1.189 on May 28, 2021 (86 FR 28916), to describe an approach that is acceptable to the NRC staff to meet the regulatory requirements in the NRC's regulations governing a civilian nuclear power generating plant's fire protection program. Revision 5 to RG 1.189 is being issued to correct typographic errors that previously appeared in Section 5.3.1.1, ''Protection for the Safe-Shutdown Success Path,'' in RG 1.189, Revision 4. This section contains two paragraphs that were incorrectly labeled. On page 79 of the RG, the paragraph currently identified as ''c'' is incorrect, in that, that paragraph is correctly part of item ''b.'' There is a conforming change where the current ''d'' should be ''c.'' In addition, RG 1.189 contains edits to conform with the current template for RGs and fixes to a few reference numbering errors. The changes in Revision 5 are intended to improve clarity and do not substantially alter the staff's regulatory guidance.

As noted in the **Federal Register** on December 9, 2022 (87 FR 75671), this document is being published in the ''Rules'' section of the **Federal Register** to comply with publication requirements under 1 CFR chapter I.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

Issuance of RG 1.189, Revision 5, does not constitute backfitting as defined in section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Backfitting'' (Backfit Rule), and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52. The changes in Revision 5 of RG 1.189 are limited to editorial changes to improve clarity and the correction of a title. These changes do not fall within the kinds of agency actions that constitute backfitting or are subject to limitations in the issue finality

provisions of part 52. Accordingly, the NRC did not address the Backfit Rule or issue finality provisions of part 52.

V. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the development of new RGs. Suggestions can be submitted on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.* Suggestions will be considered in future updates and enhancements to the ''Regulatory Guide'' series.

Dated: November 2, 2023.

For the Nuclear Regulatory Commission.

Stephen M. Wyman,

Acting Chief, Regulatory Guide and Programs, Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2023–24621 Filed 11–7–23; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 748

[Docket No. 231010–0244]

RIN 0694–AJ39

Existing Validated End-User Authorizations in the People's Republic of China: Samsung China Semiconductor Co. Ltd. and SK hynix Semiconductor (China)) Ltd; Correction

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Correcting amendment.

SUMMARY: The Bureau of Industry and Security (BIS) published a rule in the **Federal Register** on October 17, 2023, that amended the Export Administration Regulations (EAR) to revise the existing Validated End-User (VEU) list for the People's Republic of China (PRC) for Samsung China Semiconductor Co. Ltd. and SK hynix Semiconductor (China) Ltd. That rule inadvertently omitted two amendments to the list of VEUs, which resulted in failure to add a word to the description of eligible items for SK Hynix Semiconductor (China) Ltd.; as well as the failure to remove the entry for SK hynix Semiconductor (Wuxi), which was necessary because SK hynix Semiconductor (Wuxi) recently merged with SK hynix Semiconductor (China) Ltd. This rule corrects both omissions.

DATES: This rule is effective November 8, 2023.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, U.S. Department of Commerce, Phone: 202–482–5991; Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION: The Bureau of Industry and Security (BIS) published in the **Federal Register** of October 17, 2023, in FR Doc. 2023–22873, starting on page 71478, amendments to the Export Administration Regulations (EAR) to revise the existing Validated End-User (VEU) list for the People's Republic of China (PRC) for Samsung China Semiconductor Co. Ltd. and SK hynix Semiconductor (China)) Ltd.

This rule corrects for two inadvertently omitted amendments to update the list of VEUs: the first correction adds a word to the description of eligible items for SK Hynix Semiconductor (China) Ltd.; and the second removes the entry for SK hynix Semiconductor (Wuxi) Ltd., which recently merged with SK hynix Semiconductor (China) Ltd., thereby making the entry for SK hynix Semiconductor (Wuxi) Ltd. duplicative.

Correction

BIS amends the EAR's ''Supplement No. 7 to Part 748—Authorization Validated End-User (VEU): List of Validated End-Users, Respective Items Eligible for Export, Reexport and Transfer (In-Country), and Eligible Destinations'':

- by adding the word ''therefor,'' after the word ''technology'' in the description in the ''Eligible items (by ECCN)'' column for ''SK hynix Semiconductor (China) Ltd.''; and
- by removing the entry for ''SK hynix Semiconductor (Wuxi) Ltd.'' in ''China (People's Republic of)''.

List of Subjects in 15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, part 748 of the EAR (15 CFR parts 730–774) is corrected by making the following correcting amendments:

PART 748—[AMENDED]

■ 1. The authority citation for part 748 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 4, 2022, 87 FR 48077 (August 5, 2021).

■ 2. Amend supplement no. 7 to part 748 under ''China (People's Republic of)'' by:

■ a. Revising the entry for ''SK hynix Semiconductor (China) Ltd''; and

■ b. Removing the entry for ''SK hynix Semiconductor (Wuxi) Ltd''.

The revision reads as follows:

SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU): LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER (IN-COUNTRY), AND ELIGIBLE DESTINATIONS

Country	Validated end-user	Eligible items (by ECCN)	Eligible destination	**Federal Register** citation
*	*	*	*	*
China	* * * * *			
	SK hynix Semiconductor (China) Ltd.	All items subject to the Export Administration Regulations, except ''extreme ultraviolet'' (''EUV'') equipment and ''specially designed'' ''parts,'' ''components,'' ''software,'' and ''technology'' therefor, necessary for the ''development'' or ''production'' of dynamic random-access memory (DRAM). Excluded from §§ 744.6(c)(2)(i)–(iii) and 744.23(a)(1)(iii) and (a)(2)(iii) of the EAR. See § 748.15(d).	SK hynix Semiconductor (China) Ltd., Lot K7, Wuxi High-tech Zone, Comprehensive Bonded Zone, Wuxi New District, Jiangsu Province, China 214028.	78 FR 41291, 7/10/13. 78 FR 69535, 11/20/13. 79 FR 30713, 5/29/14. 80 FR 11863, 3/5/15. 88 FR 71478, 10/17/23.

SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU): LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER (IN-COUNTRY), AND ELIGIBLE DESTINATIONS—Continued

Country	Validated end-user	Eligible items (by ECCN)	Eligible destination	**Federal Register** citation
*	*	*	*	*	*	*

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2023–23312 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General Licenses 3I, 5M, 9H, 43, 44, and 45

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of Web General Licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing six general licenses (GLs) issued pursuant to the Venezuela Sanctions Regulations: GLs 3I, 5M, 9H, 43, 44, and 45, each of which was previously made available on OFAC's website.

DATES: GLs 3I, 5M, 9H, 43, 44, and 45 were issued on October 18, 2023. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov.*

Background

On October 18, 2023, OFAC issued GLs 3I, 5M, 9H, 43, 44, and 45 to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations (VSR), 31 CFR part 591, or authorities incorporated therein. Each GL was made available on OFAC's website (*https://ofac.treasury.gov*) when it was issued. GL 3I supersedes GL 3H, which was issued on May 12, 2020. GL 5M supersedes GL 5L, which was issued on July 19, 2023. GL 9H supersedes GL 9G, which was issued May 12, 2020. GL 44 has an expiration date of April 18, 2024. The text of these GLs is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 3I

Authorizing Transactions Related to, Provision of Financing for, and Other Dealings in Certain Bonds

(a) Except as provided in paragraphs (e) and (f) of this general license, all transactions related to, the provision of financing for, and other dealings in bonds specified in the Annex to this general license (GL 3I Bonds) that would be prohibited by Subsection 1(a)(iii) of Executive Order (E.O.) 13808 of August 24, 2017 or by E.O. 13850 of November 1, 2018, each as amended by E.O. 13857 of January 25, 2019, or by E.O. 13884 of August 5, 2019, as collectively incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized, including, on or after October 18, 2023, divestment or transfer of, or facilitation of divestment or transfer of, any holdings in such bonds to a U.S. person.

(b) Except as provided in paragraph (f) of this general license, U.S. persons are authorized to engage in all transactions prohibited by Subsection 1(a)(iii) of E.O. 13808 or by E.O. 13850, each as amended, or by E.O. 13884, as collectively incorporated into the VSR, that are ordinarily incident and necessary to facilitating, clearing, and settling trades of holdings in GL 3I Bonds, provided such trades were placed prior to 4:00 p.m. eastern standard time on February 1, 2019.

(c) Except as provided in paragraph (f) of this general license, all transactions and activities prohibited by Subsection 1(a)(iii) of E.O. 13808 or by E.O. 13850, each as amended, or by E.O. 13884, as collectively incorporated into the VSR, that are ordinarily incident and necessary to the wind down of financial contracts or other agreements that were entered into prior to 4:00 p.m. eastern standard time on February 1, 2019, involving, or linked to, GL 3I Bonds are authorized. This authorization is valid through 12:01 a.m. eastern daylight time, March 31, 2020.

(d) Except as provided in paragraph (f) of this general license, all transactions related to, the provision of financing for, and other dealings in bonds that were issued both (i) prior to August 25, 2017 (the effective date of E.O. 13808), and (ii) by U.S. person entities owned or controlled, directly or indirectly, by the Government of Venezuela, other than PDV Holding, Inc. (PDVH), CITGO Holding, Inc., and any of their subsidiaries, that would be prohibited by E.O. 13808 or E.O. 13850, each as amended, or by E.O. 13884, as collectively incorporated into the VSR, are authorized.

(e) Paragraph (a) of this general license does not authorize U.S. persons to sell, or to facilitate the sale of, GL3I Bonds to, directly or indirectly, any person whose property and interests in property are blocked pursuant to the VSR.

(f) This general license does not authorize:

(1) The unblocking of any property blocked pursuant to the VSR, or any other part of 31 CFR chapter V, except as authorized by paragraphs (a), (b), (c), and (d); or

(2) Any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V, or any transactions or activities with any blocked persons other than transactions or activities involving the Government of Venezuela, including Banco Central de Venezuela, that are described in this general license.

(g) Effective October 18, 2023, General License No. 3H, dated May 12, 2020, is replaced and superseded in its entirety by this General License No. 3I.

Bradley T. Smith,

Director,

Office of Foreign Assets Control.

Dated: October 18, 2023.

Annex—Venezuela-Related Bonds Described in Paragraph (a) of General License 3I (GL 3I Bonds)

List of GL 3I Bonds, as of October 18, 2023:

ISIN	CUSIP	Issuer name	Cpn	Issue date	Maturity
XS0082274118	EC0634765	Pulp & Paper International Invts Ltd	8.5	12/2/1997	12/2/2002
XS0838835451	EJ4041160	Republic of Venezuela 11.75% Euro-Dollar Bonds 2026 Ltd/The.	11.75	10/3/2012	10/21/2026
XS0504851535	EI2372072	Republic of Venezuela 8.25% Bonds 2024 Ltd/The	8.25	4/30/2010	10/13/2024
XS0838864808	EJ4040618	Republic of Venezuela 8.25% Bonds 2024 Ltd/The	8.25	10/3/2012	10/13/2024
USN7992HAA07	EF3856640	Sidetur Finance BV	10	5/3/2006	4/20/2016
US825870AA62	825870AA6	Sidetur Finance BV	10	5/3/2006	4/20/2016
XS0081483090	922655BR5	Venezuela Global Strip	0	9/18/1997	9/15/2017
XS0081484817	GG7366808	Venezuela Global Strip	0	9/18/1997	9/15/2021
XS0081487166	922655CJ2	Venezuela Global Strip	0	9/18/1997	3/15/2026
XS0081483843	922655BV6	Venezuela Global Strip	0	9/18/1997	9/15/2019
XS0081483504	922655BU8	Venezuela Global Strip	0	9/18/1997	3/15/2019
XS0081486861	922655CH6	Venezuela Global Strip	0	9/18/1997	9/15/2025
XS0081484064	922655BW4	Venezuela Global Strip	0	9/18/1997	3/15/2020
XS0081483413	922655BT1	Venezuela Global Strip	0	9/18/1997	9/15/2018
XS0081487240	922655CK9	Venezuela Global Strip	0	9/18/1997	9/15/2026
XS0081486515	922655CG8	Venezuela Global Strip	0	9/18/1997	3/15/2025
XS0081484908	922655CA1	Venezuela Global Strip	0	9/18/1997	3/15/2022
XS0081485202	922655CB9	Venezuela Global Strip	0	9/18/1997	9/15/2022
XS0081485467	922655CD5	Venezuela Global Strip	0	9/18/1997	9/15/2023
XS0081483330	922655BS3	Venezuela Global Strip	0	9/18/1997	3/15/2018
XS0081486192	922655CF0	Venezuela Global Strip	0	9/18/1997	9/15/2024
XS0081484221	922655BX2	Venezuela Global Strip	0	9/18/1997	9/15/2020
XS0081485541	922655CE3	Venezuela Global Strip	0	9/18/1997	3/15/2024
XS0081484650	922655BY0	Venezuela Global Strip	0	9/18/1997	3/15/2021
XS0081485384	922655CC7	Venezuela Global Strip	0	9/18/1997	3/15/2023
XS0081487679	922655CL7	Venezuela Global Strip	0	9/18/1997	3/15/2027
XS0081469008	922655CS2	Venezuela Global Strip	0	9/18/1997	9/15/2027
XS0081487836	922655CM5	Venezuela Global Strip	0	9/18/1997	9/15/2027
XS0081469859	922655CR4	Venezuela Global Strip	0	(*)	9/15/2027
XS0081488644	922655CQ6	Venezuela Global Strip	0	(*)	9/15/2027
XS0029484788	EF3043504	Venezuela Government International Bond	0	12/18/1990.	4/15/2020
XS0029484861	EF3042142	Venezuela Government International Bond	0	12/18/1990.	4/15/2020
XS0029484515	EF3043546	Venezuela Government International Bond	0	12/18/1990.	4/15/2020
XS0029485322	TT3352321	Venezuela Government International Bond	0	12/18/1990.	4/15/2020
XS0029484945	TT2005359	Venezuela Government International Bond	0	12/18/1990.	4/15/2020
US922646AS37	922646AS3	Venezuela Government International Bond	9.25	9/18/1997	9/15/2027
US922646AT10	922646AT1	Venezuela Government International Bond	13.625	8/6/1998	8/15/2018
USP9395PAA95	EF5132735	Venezuela Government International Bond	13.625	9/27/2001	8/15/2018
US922646BE32	922646BE3	Venezuela Government International Bond	13.625	9/27/2001	8/15/2018
USP97475AD26	ED2379482	Venezuela Government International Bond	7	12/1/2003	12/1/2018
US922646BL74	922646BL7	Venezuela Government International Bond	9.375	1/14/2004	1/13/2034
XS0217249126	ED8955574	Venezuela Government International Bond	7.65	4/21/2005	4/21/2025
USP97475AG56	EF1877168	Venezuela Government International Bond	6	12/9/2005	12/9/2020
USP97475AJ95	EH0305910	Venezuela Government International Bond	7	11/15/2007.	3/31/2038
USP17625AB33	EH3345228	Venezuela Government International Bond	9.25	5/7/2008	5/7/2028
USP17625AA59	EH3344783	Venezuela Government International Bond	9	5/7/2008	5/7/2023
USP97475AN08	EH9901297	Venezuela Government International Bond	7.75	10/13/2009.	10/13/2019
USP97475AP55	EH9901214	Venezuela Government International Bond	8.25	10/13/2009.	10/13/2024
USP17625AC16	EI3500440	Venezuela Government International Bond	12.75	8/23/2010	8/23/2022
USP17625AD98	EI7507573	Venezuela Government International Bond	11.95	8/5/2011	8/5/2031
USP17625AE71	EI8410553	Venezuela Government International Bond	11.75	10/21/2011.	10/21/2026

N/A Field Not Applicable.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 5M

Authorizing Certain Transactions Related to the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond on or After January 18, 2024

(a) Except as provided in paragraph (b) of this general license, on or after January 18, 2024, all transactions related to, the provision of financing for, and other dealings in the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond that would be prohibited by subsection l(a)(iii) of Executive Order (E.O.) 13835 of May 21, 2018, as amended by E.O. 13857 of January 25, 2019, and incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized.

(b) This general license does not authorize any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V.

(c) Effective October 18, 2023, General License No. 5L, dated July 19, 2023, is replaced and superseded in its entirety by this General License No. 5M.

Bradley T. Smith,

Director,

Office of Foreign Assets Control.

Dated: October 18, 2023.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 9H

Authorizing Transactions Related to Dealings in Certain Securities

(a) Except as provided in paragraphs (f) and (g) of this general license, all transactions and activities prohibited by Subsection 1(a)(iii) of Executive Order (E.O.) 13808 of August 24, 2017 or by E.O. 13850 of November 1, 2018, each as amended by E.O. 13857 of January 25, 2019, or by E.O. 13884 of August 5, 2019, as collectively incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), that are ordinarily incident and necessary to dealings in any debt (including the bonds listed on the Annex to this general license, promissory notes, and other receivables) of, or any equity in, Petróleos de Venezuela, S.A. (PdVSA) or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, issued prior to August 25, 2017 (the effective date of E.O. 13808) (together, ''PdVSA Securities''), are authorized, including, on or after October 18, 2023, divestment or transfer of, or facilitation of divestment or transfer of, any holdings in such PdVSA Securities to a U.S. person.

(b) The transactions and activities authorized in paragraph (a) include facilitating, clearing, and settling transactions to divest PdVSA Securities, including on behalf of U.S. persons.

(c) Except as provided in paragraph (g) of this general license, all transactions and activities prohibited by Subsection 1(a)(iii) of E.O. 13808 or by E.O. 13850, each as amended, or by E.O. 13884, as collectively incorporated into the VSR, that are ordinarily incident and necessary to facilitating, clearing, and settling trades of holdings in PdVSA Securities are authorized, provided such trades were placed prior to 4:00 p.m. eastern standard time on January 28, 2019.

(d) Except as provided in paragraph (g) of this general license, all transactions and activities prohibited by Subsection 1(a)(iii) of E.O. 13808 or by E.O 13850, each as amended, or by E.O. 13884, as collectively incorporated into the VSR, that are ordinarily incident and necessary to the wind down of financial contracts or other agreements that were entered into prior to 4:00 p.m. eastern standard time on January 28, 2019, involving, or linked to, PdVSA Securities are authorized. This authorization is valid through 12:01 a.m. eastern daylight time, March 31, 2020.

(e) Except as provided in paragraph (g) of this general license, all transactions and activities prohibited by Subsection 1(a)(iii) of E.O. 13808 or by E.O. 13850, each as amended, or by E.O. 13884, as collectively incorporated into the VSR, that are ordinarily incident and necessary to dealings in any bonds that were issued prior to August 25, 2017 (the effective date of E.O. 13808) by the following entities or any of their subsidiaries, are authorized:

- PDV Holdings, Inc.
- CITGO Holdings, Inc.

(f) Paragraph (a) of this general license does not authorize U.S. persons to sell, or to facilitate the sale of, PdVSA Securities to, directly or indirectly, any person whose property and interests in property are blocked pursuant to the VSR.

(g) This general license does not authorize:

(1) The unblocking of any property blocked pursuant to the VSR, or any other part of 31 CFR chapter V, except as authorized by paragraphs (a), (c), (d), and (e); or

(2) Any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V, or any transactions or activities with any blocked persons other than transactions or activities involving Government of Venezuela, including Banco Central de Venezuela, PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, that are described in this general license.

(h) Effective October 18, 2023, General License No. 9G, dated May 12, 2020, is replaced and superseded in its entirety by this General License No. 9H.

Bradley T. Smith,

Director,

Office of Foreign Assets Control.

Dated: October 18, 2023.

Annex—Bonds Described in Paragraph (a) of General License 9H List of Bonds

Described in Paragraph (a) of General License 9H, as of October 18, 2023:

ISIN	CUSIP	Issuer name	Cpn	Issue date	Maturity
XS0294364954	EG3110533	Petroleos de Venezuela SA	5.375	4/12/2007	4/12/2027
XS0294367205	EG3110772	Petroleos de Venezuela SA	5.5	4/12/2007	4/12/2037
USP7807HAK16	EI4173619	Petroleos de Venezuela SA	8.5	10/29/2010	11/2/2017
US716558AB79	716558AB7	Petroleos de Venezuela SA	8.5	10/29/2010	11/2/2017
US716558AC52	716558AC5	Petroleos de Venezuela SA	12.75	2/17/2011	2/17/2022
USP7807HAM71	EI5787318	Petroleos de Venezuela SA	12.75	2/17/2011	2/17/2022
US716558AD36	716558AD3	Petroleos de Venezuela SA	9	11/17/2011	11/17/2021
USP7807HAP03	EI8799468	Petroleos de Venezuela SA	9	11/17/2011	11/17/2021
USP7807HAQ85	EJ1968233	Petroleos de Venezuela SA	9.75	5/17/2012	5/17/2035
US716558AE19	716558AE1	Petroleos de Venezuela SA	9.75	5/17/2012	5/17/2035
USP7807HAR68	EJ9776299	Petroleos de Venezuela SA	6	11/15/2013	11/15/2026
US716558AF83	716558AF8	Petroleos de Venezuela SA	6	11/15/2013	11/15/2026
USP7807HAT25	EK2909308	Petroleos de Venezuela SA	6	5/16/2014	5/16/2024

ISIN	CUSIP	Issuer name	Cpn	Issue date	Maturity
US716558AG66	716558AG6	Petroleos de Venezuela SA	6	5/16/2014	5/16/2024
XS1126891685	JV9618804	Petroleos de Venezuela SA	6	10/28/2014	10/28/2022
USP7807HAV70	QZ9940003	Petroleos de Venezuela SA	8.5	10/28/2016	10/27/2020
US716558AH40	716558AH4	Petroleos de Venezuela SA	8.5	10/28/2016	10/27/2020
USG70415AC18	DD0110070	Petrozuata Finance Inc	8.37	6/27/1997	10/1/2022
US71676QAE61	71676QAE6	Petrozuata Finance Inc	8.37	6/27/1997	10/1/2022
USG2025MAB75	CP5100153	Cerro Negro Finance Ltd	7.9	6/18/1998	12/1/2020
US156877AC63	156877AC6	Cerro Negro Finance Ltd	8.03	6/18/1998	6/1/2028
USG2025MAC58	CP5100211	Cerro Negro Finance Ltd	8.03	6/18/1998	6/1/2028
US156877AB80	156877AB8	Cerro Negro Finance Ltd	7.9	6/18/1998	12/1/2020
XS0356521160	EH2888749	CA La Electricidad de Caracas	8.5	4/10/2008	4/10/2018

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 43

Authorizing Transactions Involving CVG Compania General de Mineria de Venezuela CA

(a) Except as provided in paragraph (b) of this general license, all transactions involving CVG Compania General de Mineria de Venezuela CA (Minerven), or any entity in which Minerven owns, directly or indirectly, a 50 percent or greater interest, that are prohibited by Executive Order (E.O.) 13850, as amended by E.O. 13857, or E.O. 13884, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized.

(b) This general license does not authorize any transactions otherwise prohibited by the VSR, including any transactions involving any person blocked pursuant to the VSR other than the blocked persons described in paragraph (a) of this general license, Government of Venezuela persons blocked solely pursuant to E.O. 13884, Banco Central de Venezuela, or Banco de Venezuela SA Banco Universal.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

Dated: October 18, 2023.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 44

Authorizing Transactions Related to Oil or Gas Sector Operations in Venezuela

(a) Except as provided in paragraph (b) of this general license, all transactions prohibited by the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), including transactions involving Petróleos de Venezuela, S.A. (PdVSA) or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest (collectively, ''PdVSA Entities''), that are related to oil or gas sector operations in Venezuela are authorized through 12:01 a.m. eastern daylight time, April 18, 2024, including:

(1) Production, lifting, sale, and exportation of oil or gas from Venezuela, and provision of related goods and services;

(2) Payment of invoices for goods or services related to oil or gas sector operations in Venezuela; ·

(3) New investment in oil or gas sector operations in Venezuela; and

(4) Delivery of oil and gas from Venezuela to creditors of the Government of Venezuela, including creditors of PdVSA Entities, for the purpose of debt repayment.

(b) This general license does not authorize:

(1) Any transactions involving any financial institution blocked pursuant to Executive Order (E.O.) 13850 other than Banco Central de Venezuela or Banco de Venezuela SA Banco Universal;

(2) The provision of goods or services to, or new investment in, an entity located in Venezuela that is owned or controlled by, or a joint venture with, an entity located in the Russian Federation;

(3) Any transactions related to new investment in oil or gas sector operations in Venezuela by a person located in the Russian Federation or any entity owned or controlled by a person located in the Russian Federation;

(4) Any transactions prohibited by subsections l(a)(i)–(iii) or l(b) of E.O. 13808, other than the transactions described in paragraphs (a)(2) and (a)(4) of this general license;

(5) Any transactions prohibited by E.O. 13827 or E.O. 13835; or

(6) The unblocking of any property blocked pursuant to the VSR.

Note to General License No. 44. Nothing in this general license relieves any person from compliance with the requirements of other Federal agencies, including the Department of Commerce's Bureau of Industry and Security.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

Dated: October 18, 2023.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 45

Authorizing Certain Repatriation Transactions Involving Consorcio Venezolano de Industrias Aeronáuticas y Servicios Aéreos, S.A.

(a) Except as provided in paragraph (b) of this general license, all transactions ordinarily incident and necessary to the repatriation of Venezuelan nationals from non-U.S. jurisdictions in the Western Hemisphere to Venezuela, and are exclusively for the purposes of such repatriation, involving Consorcio Venezolano de Industrias Aeronáuticas y Servicios Aéreos, S.A. (Conviasa), or any entity in which Conviasa owns, directly or indirectly, a 50 percent or greater interest, that are prohibited by Executive Order (E.O.) 13850, as amended by E.O. 13857, or E.O. 13884, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized.

(b) This general license does not authorize any transactions otherwise prohibited by the VSR, including any transactions involving any person blocked pursuant to the VSR other than the blocked persons described in paragraph (a) of this general license, Government of Venezuela persons blocked solely pursuant to E.O. 13884, Banco Central de Venezuela, or Banco de Venezuela SA Banco Universal.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

Dated: October 18, 2023.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2023–24831 Filed 11–6–23; 4:15 pm]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 1010

RIN 1506–AB49

Use of FinCEN Identifiers for Reporting Beneficial Ownership Information of Entities

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Final rule.

SUMMARY: FinCEN is issuing a final rule to specify when and how entities required to report beneficial ownership information to FinCEN may use a FinCEN identifier to report the beneficial ownership information of certain related entities. These regulations amend FinCEN's Beneficial Ownership Information Reporting Requirements Rule, which implements Section 6403 of the Corporate Transparency Act (CTA). The CTA was enacted into law as part of the Anti-Money Laundering Act of 2020 (AML Act), which is itself part of the National Defense Authorization Act for Fiscal Year 2021 (NDAA).

DATES: This rule is effective January 1, 2024.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Support Section at 1–800–767–2825 or electronically at *frc@fincen.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

This final rule sets out certain amendments to FinCEN's Beneficial Ownership Information Reporting Requirements Rule [1] (the Final Reporting Rule), which implements Section 6403 of the Corporate Transparency Act (CTA), to specify when and how entities required to report beneficial ownership information (BOI) to FinCEN may use a FinCEN identifier to report the BOI of certain related entities. The amendments specify how such entities may use an entity's FinCEN identifier to fulfill their BOI reporting obligations under 31 CFR 1010.380.

II. Background

On December 8, 2021, FinCEN published a notice of proposed rulemaking for the Beneficial Ownership Information Reporting Requirements (the Reporting NPRM).[2] The Reporting NPRM proposed regulations specifying what BOI must be reported to FinCEN pursuant to CTA requirements, by whom, and when. In addition, the Reporting NPRM proposed processes for obtaining, updating, and using FinCEN identifiers. The Reporting NPRM included a 60-day comment period, which closed on February 7, 2022, and FinCEN received over 240 comments on the NPRM, including multiple comments about the proposed processes for obtaining, updating, and using FinCEN identifiers.

On September 30, 2022, FinCEN published the Final Reporting Rule, with an effective date of January 1, 2024.[3] The Final Reporting Rule requires certain corporations, limited liability companies, and other similar entities (collectively, ''reporting companies'') [4] to report certain identifying information about the beneficial owners who own or control such entities and the company applicants who form or register them.[5] These requirements are intended to facilitate access to BOI for certain authorized recipients, including law enforcement and regulators, for the purposes of countering money laundering and the financing of terrorism, and for other specific purposes.[6] The Final Reporting Rule requires reporting companies to report to FinCEN within prescribed time periods information about themselves, as well as information about two categories of individuals: (1) the beneficial owners of the reporting company; and (2) the company applicants, who are the individuals who filed a document to create the reporting company or register it to do business.

The Final Reporting Rule also established the rules for individuals and entities to obtain and update FinCEN identifiers, and the rules for use of an individual's FinCEN identifier. However, FinCEN declined to finalize the portion of the proposed rule pertaining to the use of an entity's FinCEN identifier. Rather, FinCEN re-proposed a small part of the Reporting NPRM pertaining to the use of reporting companies' FinCEN identifiers for public comment on December 16, 2022,[7] as part of the notice of proposed rulemaking on Beneficial Ownership Information Access and Safeguards, and Use of FinCEN Identifiers for Entities (the Access NPRM).

A FinCEN identifier is a unique identifying number that FinCEN will issue to individuals who have provided FinCEN with their BOI and to reporting companies that have filed initial BOI reports.[8] In the discussion that follows, FinCEN will refer to these as ''individual FinCEN identifiers'' and ''entity FinCEN identifiers,'' respectively. The Final Reporting Rule finalized the use of individual FinCEN identifiers but not the use of entity FinCEN identifiers. Concerning the latter, the CTA specifies that if an individual ''is or may be a beneficial owner of a reporting company by an interest held by the individual in an entity that, directly or indirectly, holds an interest in the reporting company,'' the reporting company may report the appropriate entity's FinCEN identifier in lieu of providing the individual's BOI.[9]

FinCEN originally proposed incorporating this language in the Reporting NPRM without significant alteration or clarification. Some commenters to the Reporting NPRM, however, expressed concerns that the use of entity FinCEN identifiers could obscure the identities of beneficial owners in a manner that might result in greater secrecy or incomplete or misleading disclosures. Several commenters noted that the proposed language could be confusing. Others highlighted problems that could arise when the FinCEN identifier is used for reporting companies with ownership structures that involve multiple beneficial owners and intermediate entities. Persuaded by these comments, FinCEN did not adopt the proposed language in the Final Reporting Rule. Instead, FinCEN proposed new language in the Access NPRM establishing how reporting companies could use an entity's FinCEN identifier. Comments received in response to the Access NPRM both addressed this new proposal and raised other issues about entity FinCEN identifiers.

III. Use of FinCEN Identifiers for Entities

Proposed Rule. Proposed 31 CFR 1010.380(b)(4)(ii)(B) provided that a reporting company may report another

[1] Treasury, FinCEN, Beneficial Ownership Information Reporting Requirements, 87 FR 59498 (Sept. 30, 2022).

[2] *See* U.S. Department of the Treasury (Treasury), FinCEN, Beneficial Ownership Information Reporting Requirements, 86 FR 69920 (December 8, 2021).

[3] The Reporting Rule is the first in a series of rulemakings to implement the CTA, enacted on January 1, 2021, as part of the Anti-Money Laundering Act of 2020 and codified at 31 U.S.C. 5336. The CTA is Title LXIV of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283 (Jan. 1, 2021) (the NDAA). Division F of the NDAA is the Anti-Money Laundering Act of 2020, which includes the CTA.

[4] *See* 31 U.S.C. 5336(a)(11).

[5] *See* Treasury, FinCEN, Beneficial Ownership Information Reporting Requirements, 87 FR 59498, 59498–99 (Sept. 30, 2022).

[6] Public Law 116–283, Section 6402 (Jan. 1, 2021).

[7] 87 FR 77404 (Dec. 16, 2022).

[8] 31 U.S.C. 5336(b)(3).

[9] 31 U.S.C. 5336(b)(3)(C).

entity's FinCEN identifier and full legal name in lieu of the information required under 31 CFR 1010.380(b)(1) with respect to the beneficial owners of the reporting company, but only if three conditions are met: (1) the entity has obtained a FinCEN identifier and provided that FinCEN identifier to the reporting company; (2) an individual is or may be a beneficial owner of the reporting company by virtue of an interest in the reporting company that the individual holds through the entity; and (3) the beneficial owners of the entity and of the reporting company are the same individuals.[10] This proposal reflected FinCEN's understanding that use of the entity FinCEN identifier would best satisfy the CTA's overall statutory scheme—in which reporting the intermediate entity's FinCEN identifier would be equivalent to reporting the BOI of the reporting company's beneficial owners—only if the two entities in fact had the same beneficial owners.

Comments Received. Several comments supported FinCEN's proposed formulation for reporting company use of entity FinCEN identifiers, noting that this approach reduced the risk that an entity FinCEN identifier could be used in ways that would obscure a reporting company's true beneficial owners. This had been a significant concern of commenters that were critical of FinCEN's initial formulation in the Reporting NPRM. While generally supportive, two commenters proposed specific changes to the regulatory text to clarify FinCEN's revised approach and to specify that an entity FinCEN identifier could no longer be used if the BOI of either the reporting company or the entity whose FinCEN identifier was reported changed such that the two were no longer identical. Other commenters, without stating a position on FinCEN's proposed specification of three limiting criteria for an entity's use of a FinCEN identifier, expressed skepticism about the wisdom or desirability of both the entity FinCEN identifiers and the individual FinCEN identifiers in general. Others posed specific implementation questions, such as how a reporting company can be expected to verify FinCEN identifier information provided by a beneficial owner. One commenter questioned the value of allowing use of an entity FinCEN identifier when an individual is ''or may be'' a beneficial owner of a reporting company by virtue of an interest held in an intermediate entity, notwithstanding the fact that the phrase is in the CTA itself. Finally, commenters requested that FinCEN permit corporate service providers to apply for entity FinCEN identifiers on others' behalf.

Final Rule. FinCEN adopts the proposed rule, with certain revisions. The final rule incorporates changes to clarify the circumstances in which an entity FinCEN identifier could be used. These changes, which were specifically suggested by commenters, are: (1) to consistently refer to the entity whose FinCEN identifier the reporting company may use as ''another entity'' or ''the other entity'' rather than simply ''the entity,'' in order to avoid confusion with the reporting company itself; and (2) to make clear that it is an individual's *ownership* interest in another entity that allows the reporting company to report the other entity's FinCEN identifier in lieu of the individual's information. FinCEN considers both of these changes to improve the clarity of the provision and make it more likely that reporting companies will use the FinCEN identifier as intended.

At the same time, however, FinCEN has not adopted all of the revisions suggested by commenters. For example, FinCEN has not removed the regulatory text that allows use of an entity FinCEN identifier if a beneficial owner of the entity ''may be'' a beneficial owner of the reporting company by virtue of an interest held in an intermediate entity. As noted above, the CTA expressly permits this, and FinCEN retains the clause to give effect to the principle that a reporting company should be able to report an entity FinCEN identifier when it has a good faith belief that the use is appropriate.

FinCEN also declines to change the rule text to more specifically address the requirement that a reporting company update its BOI report if the beneficial owners of the entity whose entity FinCEN identifier the reporting company has previously reported cease to be the same as the beneficial owners of the reporting company. FinCEN believes that the language as proposed is already sufficiently clear on this point. The commenters who raised this issue correctly understand that if at any time the reportable beneficial owners of either the reporting company or the entity whose FinCEN identifier was reported changes such that the two are no longer identical, then the reporting company must file an update with FinCEN and can no longer report the relevant entity's FinCEN identifier. That the commenters understood this requirement suggests that additional clarification is not necessary and, if appropriate, FinCEN may consider clarifying this requirement in the context of guidance or FAQs.

Finally, with respect to the comments that questioned whether the entity FinCEN identifier would actually be of use or value to reporting companies, FinCEN has acknowledged that it can only speculate as to the likely rate at which reporting companies will request entity FinCEN identifiers and the likelihood that they will report entity FinCEN identifiers in lieu of information about individual beneficial owners. FinCEN will monitor developments on this subject closely as the Final Reporting Rule is implemented.

IV. Regulatory Analysis

This rule is necessary to comply with and implement the CTA and is consistent with the CTA's statutory mandate that FinCEN issue regulations regarding access to beneficial ownership information.[11] Specifically, the rule amends the BOI reporting regulations to implement the provision of the CTA regarding the use of FinCEN identifiers codified at 31 U.S.C. 5336(b)(3)(C). The amendments specify how reporting companies would be able to use an entity's FinCEN identifier to fulfill their BOI reporting obligations under 31 CFR 1010.380. In particular, the rule establishes a process through which a reporting company may report another reporting company's entity FinCEN identifier and full legal name in lieu of the information otherwise required under 31 CFR 1010.380(b)(1), subject to certain limitations.

This rule affects reporting companies that choose to report the entity FinCEN identifier of another reporting company in their BOI report. It may also affect reporting companies deciding whether to request an entity FinCEN identifier.

FinCEN has analyzed the final rule as required under Executive Orders 12866, 13563, and 14094, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, and the Paperwork Reduction Act. This final rule will not have an annual effect on the economy of $200 million or otherwise constitute a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, as amended. Pursuant to the Regulatory Flexibility Act, FinCEN certifies that this rule will not have a significant economic impact on a substantial number of small entities. FinCEN assessed that this rule results in no additional costs to small entities. Furthermore, pursuant to the Unfunded Mandates Reform Act, FinCEN concluded that the rule will not result

[10] 87 FR 77404 (Dec. 16, 2022).

[11] 31 U.S.C. 5336(b)(4).

in an expenditure of $177 million or more annually by State, local, and Tribal governments or by the private sector.[12] Finally, FinCEN assesses that this rule will not result in any additional burden or costs considered under the framework of the Paperwork Reduction Act (PRA).

FinCEN does not assess any additional quantifiable costs or benefits, measured in burden hours, associated with the rule beyond those separately considered in the Final Reporting Rule's regulatory impact analysis (RIA).[13] [14] Further, FinCEN assesses that the rule is consistent with the assumption in the Final Reporting Rule's RIA that the cost associated with using entities' FinCEN identifiers is accounted for in the cost estimates for the BOI report. Additionally, the rule can reduce burden for reporting companies that choose to report another reporting company's FinCEN identifier because the filing reporting company will provide fewer pieces of information on its BOI report. However, FinCEN assesses such burden reduction is likely to be minimal relative to the total cost of filling out and submitting the report. Furthermore, it is unknown to FinCEN how many entities will choose to utilize entity FinCEN identifiers, as provided for in this rule. Accordingly, FinCEN does not estimate costs or benefits associated with this rule beyond what is stated in the Final Reporting Rule RIA.

The rule is statutorily mandated, and therefore, FinCEN has limited ability to implement alternatives. Nonetheless, FinCEN considered the following alternatives that would be available under the statute: (1) implementing the statutory language at 31 U.S.C. 5336(b)(3)(C) as written; and (2) implementing the language proposed in the Reporting NPRM at 31 CFR 1010.380(b)(4)(ii)(B). However, as explained in Sections II and III, FinCEN is promulgating this final rule to address ambiguities in the statutory text and concerns raised by commenters about the clarity of the provision proposed in the Reporting NPRM and the potential for misuse of entity FinCEN identifiers.

[12] The Unfunded Mandates Reform Act requires an assessment of mandates that will result in an annual expenditure of $100 million or more, adjusted for inflation. The U.S. Bureau of Economic Analysis reports the annual value of the gross domestic product (GDP) deflator in 1995, the year of the Unfunded Mandates Reform Act, as 71.823, and as 127.224 in 2022. *See* U.S. Bureau of Economic Analysis, ''Table 1.1.9. Implicit Price Deflators for Gross Domestic Product'' (accessed Friday, June 2, 2023). Thus, the inflation adjusted estimate for $100 million is 127.224/71.823 × 100 = $177 million.

[13] *See* 87 FR 59577–59578 (Sept. 30, 2022).

[14] The Final Reporting Rule's RIA did not estimate the number of reporting companies that will obtain FinCEN identifiers. A reporting company obtains a FinCEN identifier by either checking a box on its initial BOI report or submitting an updated BOI report with the box checked. Therefore, FinCEN assumed that the cost of reporting companies obtaining FinCEN identifiers was included in the initial BOI report cost estimates in the final BOI reporting rule RIA. *See* 87 FR 59578 (Sept. 30, 2022).

List of Subjects in 31 CFR Parts 1010

Administrative practice and procedure, Aliens, Authority delegations (Government agencies), Banks and banking, Brokers, Business and industry, Commodity futures, Currency, Citizenship and naturalization, Electronic filing, Federal savings associations, Federal-States relations, Federally recognized tribes, Foreign persons, Holding companies, Indian law, Indians, Insurance companies, Investment advisers, Investment companies, Investigations, Law enforcement, Penalties, Reporting and recordkeeping requirements, Small businesses, Securities, Terrorism, Tribal government, Time.

Authority and Issuance

For the reasons set forth in the preamble, the U.S. Department of the Treasury and Financial Crimes Enforcement Network amend 31 CFR part 1010 as follows:

PART 1010—GENERAL PROVISIONS

■ 1. The authority citation for part 1010 continues to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314 and 5316–5336; title III, sec. 314, Pub. L. 107–56, 115 Stat. 307; sec. 2006, Pub. L. 114–41, 129 Stat. 458–459; sec. 701, Pub. L. 114–74, 129 Stat. 599.

■ 2. Amend § 1010.380, added September 30, 2022 at 87 FR 59498, and effective January 1, 2024, by adding paragraph (b)(4)(ii)(B) to read as follows:

§ 1010.380 Reports of beneficial ownership information.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(B) A reporting company may report another entity's FinCEN identifier and full legal name in lieu of the information required under paragraph (b)(1)(ii) of this section with respect to the beneficial owners of the reporting company only if:

(*1*) The other entity has obtained a FinCEN identifier and provided that FinCEN identifier to the reporting company;

(*2*) An individual is or may be a beneficial owner of the reporting company by virtue of an interest in the reporting company that the individual holds through an ownership interest in the other entity; and

(*3*) The beneficial owners of the other entity and of the reporting company are the same individuals.

* * * * *

Andrea M. Gacki,

Director, Financial Crimes Enforcement Network.

[FR Doc. 2023–24559 Filed 11–7–23; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0512]

RIN 1625–AA00

Safety Zone, Neuse River, New Bern, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the Neuse River in New Bern, North Carolina. This action is necessary to provide for the safety of life on these waters during an aerobatic airshow on November 25, 2023. This rule prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port (COTP) North Carolina or a designated representative.

DATES: This rule is effective November 25, 2023 from 4 through 6 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0512 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 Chief Petty Officer Elvin Rodriguez, Waterways Management Division, U.S. Coast Guard; telephone 910–772–2239, email *NCMarineevents@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 would be impracticable to publish an NPRM and consider comments without delaying promulgation of the rule beyond November 25, 2023, the date of the air show, and it would be contrary to the public interest to delay promulgation of the rule until after the event occurs. The rule needs to be in effect by November 25, 2023, to protect persons and vessels from the hazards associated with this event. Such hazards include the possibility of an aircraft striking a vessel on the surface below the flight zone.

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 to publish this rule 30 days prior to the date of the event, and contrary to the public interest to delay publication past that date because the rule must be in place to protect persons and vessels from the hazards associated with this event on November 25, 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 North Carolina (COTP) has determined that potential hazards associated with the Thanksgiving Twilight Show, scheduled for 4 through 6 p.m. on November 25, 2023, is a safety concern for mariners during the time that aircraft perform aerobatic maneuvers directly above the Neuse River. This rule is necessary to protect personnel, vessels, and the marine environment from the hazards associated with the airshow above this position of the Neuse River.

IV. Discussion of the Rule

This rule establishes a temporary safety zone on a portion of the Neuse River on November 25, 2023, from 4 to 6 p.m. The rule will be enforced for the duration of the event. The date and times of enforcement will be broadcast locally over VHF–FM marine radio. The safety zone will include all navigable waters of the Neuse River in New Bern, North Carolina inside an area starting from approximate positions: latitude 35°06′55″ N, longitude 077°02′04″ W, then east to latitude 35°07′06″ N, longitude 077°01′27″ W, then southeast to latitude 35°06′49″ N, longitude 077°01′12″ W, then south to latitude 35°06′08″ N, longitude 077°01′18″ W, then west to latitude 35°06′02″ N, longitude 077°01′57″ W, then north to latitude 35°06′32″ N, longitude 077°01′54″ W, then north to the point of origin then north to the point of origin, for a total area of approximately 1 mile square.

The airshow will consist of three separate performances and will last a total approximately 2 hours. The event will begin roughly 20 minutes before sunset and will last until approximately 30 minutes after sunset. All aircraft will remain at least 500 feet above the ground. Public spectators will be allowed to view the event from the waterway, however, for safety reasons, the aircraft will not perform if there are any vessels inside the safety zone. The duration of this safety zone is intended to protect participants and spectators on the navigable waters of the Neuse River during the airshow. Vessels may transit the area, so long as they remain outside the safety zone. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP North Carolina or a designated representative.

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, and duration of the safety zone. Vessel traffic will not be allowed to enter or transit a portion of the Neuse River during the airshow from 4 through 6 p.m. November 25, 2023. The Coast Guard will transmit a Broadcast Notice to Mariners via VHF–FM marine channel 16 regarding the enforcement area. This rule allows vessels to request permission to pass through the regulated area.

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 2 hours that will prohibit entry within a 1 square mile area of the Neuse River on November 25, 2023, from 4 to 6 p.m. 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.T05–0512 to read as follows:

§ 165.T05–0512 Safety Zone; Neuse River, Airshow, New Bern, NC.

(a) *Location.* The following area is a safety zone: all navigable waters of the Neuse River in New Bern, North Carolina, inside an area starting from approximate positions: latitude 35°06′55″ N, longitude 077°02′04″ W, then east to latitude 35°07′06″ N, longitude 077°01′27″ W, then southeast to latitude 35°06′49″ N, longitude 077°01′12″ W, then south to latitude 35°06′08″ N, longitude 077°01′18″ W, then west to latitude 35°06′02″ N, longitude 077°01′57″ W, then north to latitude 35°06′32″ N, longitude 077°01′54″ W, then north to the point of origin, for a total area of approximately 1 mile square.

(b) *Definitions.* As used in this section—

Captain of the Port (COTP) means the Commander, Sector North Carolina.

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard commissioned, warrant, or petty officer designated by the Captain of the Port North Carolina (COTP) for the enforcement of the safety zone.

(c) *Regulations.* (1) The general regulations governing safety zones in § 165.23 apply to the area described in paragraph (a) of this section.

(2) Entry into or remaining in this safety zone is prohibited unless authorized by the COTP North Carolina or the COTP North Carolina's designated representative. Unless permission to remain in the zone has been granted by the COTP North Carolina or the COTP North Carolina's designated representative, a vessel within this safety zone must immediately depart the zone when this section becomes effective.

(3) The Captain of the Port, North Carolina can be reached through the Coast Guard Sector North Carolina Command Duty Officer, Wilmington, North Carolina, at telephone number 910–343–3882.

(4) The Coast Guard and designated security vessels enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65 MHz) and channel 16 (156.8 MHz).

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement period.* This regulation will be enforced from 4 through 6 p.m. on November 25, 2023.

Timothy J. List,

Captain, U.S. Coast Guard, Captain of the Port Sector North Carolina.

[FR Doc. 2023–24713 Filed 11–7–23; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 16

[EPA–HQ–OMS–2023–0020; FRL–10620–03–OMS]

Privacy Act Regulations for EPA–100

AGENCY: Office of Inspector General, Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to revise the Agency's Privacy Act regulations to exempt a new system of records, EPA–100, OIG Data Analytics Enterprise, from certain requirements of the Privacy Act. In this rulemaking, the Agency exempts portions of this system from certain provisions of the Privacy Act because of law enforcement requirements and to avoid interference during the conduct of criminal, civil, or administrative actions or investigations. Additionally, EPA is taking direct final action to revise the

Agency's Privacy Act regulations to update the names of systems of records with general and specific exemptions, change wording to reflect that the Office of Inspector General (OIG) is an independent component of EPA, incorporate the revised citation for the Inspector General Act of 1978 and to remove specific systems of record which are no longer exempt.

DATES: This rule is effective on February 6, 2024 without further notice, unless EPA receives adverse comment by December 8, 2023. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OMS–2023–0020, at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Daniel Porter, Director, Data Analytics Directorate, Office of Inspector General, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20004; telephone number: 202–309–6449; email address: *oig.data_analytics@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is EPA using a direct final rule?

The EPA is publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. However, in the ''Proposed Rules'' section of this **Federal Register**, we are publishing a separate document that will serve as the proposed rule to exempt a new system of records, EPA–100, the OIG Data Analytics Enterprise Tracking System, from certain requirements of the Privacy Act if adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document.

If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. We would address all public comments in any subsequent final rule based on the proposed rule.

EPA is also revising the Agency's Privacy Act regulations to update the names of systems of records with general and specific exemptions. Specifically, 40 CFR 16.11, will be modified to update the name of EPA–17 from OCEFT Criminal Investigative Index and Files to Online Criminal Enforcement Activities Network (OCEAN) and EPA–40 from Inspector General's Operation and Reporting (IGOR) System Investigative Files to Inspector General Enterprise Management System (IGEMS) Investigative Module and to add EPA–100 OIG Data Analytics Enterprise. Likewise, 40 CFR 16.12 will also be modified to update the names of EPA–17 from OCEFT Criminal Investigative Index and Files to Online Criminal Enforcement Activities Network (OCEAN), EPA–21 from External Compliance Program Discrimination Complaint Files to External Compliance Case Tracking System (EXCATS), EPA–30 from OIG Hotline Allegation System to Inspector General Enterprise Management System (IGEMS) Hotline Module and EPA–40 from Inspector General's Operation and Reporting (IGOR) System Investigative Files to Inspector General Enterprise Management System (IGEMS) Investigative Module. Additionally, § 16.12 will be modified to add EPA–100 OIG Data Analytics Enterprise and to remove reference to EPA–41 because the system of records is no longer exempt.

II. General Information

The EPA will use this system of records to develop data models and analyses in order to identify fraud, waste and abuse, and programmatic problems and deficiencies. This system of records will allow the EPA OIG to identify correlations between existing EPA data sets and other government agency data sets so as to identify patterns and correlations that indicate fraud and issues of program waste and abuse. EPA OIG will apply analytics and data modeling principles within this system of records to identify problems or failures in the implementation or performance of internal controls within the EPA. The records may be used in the course of performing audits, evaluations, and inspections; investigating individuals and entities suspected of criminal, civil, or administrative misconduct and in supporting related judicial and administrative proceedings; or in conducting preliminary inquiries undertaken to determine whether to commence an audit, evaluation, inspection, or investigation.

The EPA compiles and maintains the records in the OIG Data Analytics Enterprise for use in criminal and civil investigations and actions. This system of records, EPA–100, is maintained by the Office of Inspector General. This component of EPA performs as its principal function, activities pertaining to the enforcement of criminal laws.

The Privacy Act allows Federal agencies to exempt eligible records in a system of records from certain provisions of the Act, including those that provide individuals with a right to request access to and amendment of their own records. If an agency intends to exempt a particular system of records, it must first go through the rulemaking process pursuant to 5 U.S.C. 553(b)(1)–(3), (c), and (e). This rule explains why an exemption is being claimed for this system of records and invites public comment, which EPA will consider.

Under 5 U.S.C. 552a(j)(2), the head of any agency may exempt any system of records within the agency from certain provisions of the Privacy Act, if the agency or component that maintains the system performs as its principal function any activities pertaining to the enforcement of criminal laws. The Inspector General Act mandates that the Inspector General recommend policies for, and conduct, supervise, and coordinate activities in the Agency and between the Agency and other Federal, State, and local government agencies with respect to all matters relating to the prevention and detection of fraud in programs and operations administered or financed by the Agency, and to the identification and prosecution of participants in such fraud. Under the Inspector General Act, whenever the Inspector General has reasonable grounds to believe that there has been a violation of Federal criminal law, the Inspector General must report the matter expeditiously to the Attorney General. In addition to these principal functions

pertaining to the enforcement of criminal laws, the Inspector General may receive and investigate complaints on information from various sources concerning the possible existence of activities constituting violations of law, rules, or regulations, or mismanagement, gross waste of funds, abuses of authority, or substantial and specific danger to the public health and safety. To the extent criminal law enforcement information is contained in the system as enumerated in 5 U.S.C. 552a(j)(2), the provisions of the Privacy Act from which exemptions are claimed under 5 U.S.C. 552a(j)(2) are as follows: 5 U.S.C. 552a(c)(3) and (4); 5 U.S.C. 552a(d); 5 U.S.C. 552a(e)(1), (2) and (3); 5 U.S.C. 552a(e)(4)(G) and (H); 5 U.S.C. 552a(e)(5) and (8); 5 U.S.C. 552a(f)(2) through (5); and 5 U.S.C. 552a(g).

EPA is claiming the above exemptions for the following reasons:

(1) From subsection (c)(3), because making available to a named individual an accounting of disclosures of records concerning him/her/them could reveal investigative interest on the part of EPA and/or the Department of Justice. This could allow record subjects to impede the investigation, *e.g.,* destroy evidence, intimidate potential witnesses, or flee the area to avoid inquiries or apprehension by law enforcement personnel. More broadly, the application of this provision could reveal the OIG's investigative interests, which could compromise those investigative interests. Further, such a disclosure could reveal the identity of a confidential source and hamper the Agency's investigation.

(2) From subsection (c)(4), which concerns providing notice to others regarding corrections or disputed information in accordance with subsection (d) of the Privacy Act, because no access to these records is available under subsection (d) of the Act.

(3) From subsection (d), which requires an agency to permit an individual to access, contest or request amendment of records pertaining to him/her/them, because the records contained in this system relate to official Federal investigations. Individual access to these records could compromise ongoing investigations, reveal confidential informants and/or sensitive investigative techniques used in particular investigations, or constitute unwarranted invasions of the personal privacy of third parties who are involved in a certain investigation.

(4) From subsection (e)(1), which requires an agency to maintain only relevant and necessary information about an individual, because the relevance or necessity of information obtained in the course of a law enforcement investigation is not always known when collected. Material that may seem unrelated, irrelevant, or incomplete when collected may take on added meaning or significance as the investigation progresses. Also, in the interest of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of criminal activity. Therefore, it would impede the investigative process if it were necessary to assure the relevance and necessity of all information obtained.

(5) From subsection (e)(2), which requires an agency to collect information to the greatest extent practicable directly from the subject individual when the information may result in adverse determinations about the individual's rights, benefits, or privileges under Federal programs. Application of this provision could impair investigations and law enforcement by alerting the subject of the investigation to the existence of the investigation. Further, compliance with the requirements of this subsection during the course of an investigation could impede the information gathering process or cause the destruction of evidence, thus hampering the investigation.

(6) From subsection (e)(3), which requires an agency to inform those supplying information of its authority to collect the information, its plans for using or sharing that information, and the effects of not providing the requested information. The application of this provision could provide the subject of the investigation with substantial information about the nature of the investigation, which could interfere with the investigation. To comply with the requirements of this subsection during the course of an investigation could impede the information gathering process especially when undercover operations or confidential sources are used, thus hampering the investigation.

(7) From subsections (e)(4)(G) and (H), which require an agency to publish—in the **Federal Register**—procedures concerning access to records, because no access to these records is available under subsection (d) of the Privacy Act, for the reasons explained above in the discussion of subsection (d).

(8) From subsection (e)(5), which requires an agency to maintain its records with accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual, because it is not possible to determine in advance what information is accurate, relevant, timely, and complete. Facts are first gathered and then placed into a logical order to prove or disprove objectively the criminal behavior of an individual. Material that may seem unrelated, irrelevant, or incomplete when collected may take on added meaning or significance as the investigation progresses. The restrictions of this provision could interfere with the preparation of a complete investigative report, thereby impeding effective law enforcement.

(9) From subsection (e)(8), which requires notice to an individual whenever a record on such individual is made available to others under compulsory legal process, because complying with this provision could prematurely reveal an ongoing criminal investigation to the subject of the investigation.

(10) From subsections (f)(2), (f)(3), (f)(4), and (f)(5), concerning agency rules for obtaining access to records under subsection (d), because this system is exempt from the access and amendment provisions of subsection (d). Since EPA is exempting this system of records from subsection (d) of the Act, concerning access to records, the requirements of subsections (f)(2) through (5) of the Act, concerning agency rules for obtaining access to such records, are inapplicable and are exempted to the extent that this system of records is exempted from subsection (d) of the Act.

(11) From subsection (g), which provides for civil remedies if an agency fails to comply with certain requirements of the Act applicable to a nonexempt system of records, because EPA is exempting this system of records from subsections (c)(3) and (4); (d); (e)(1), (2), (3), (4)(G), and (H), (5), and (8); and (f)(2) through (5) of the Act. The provisions of subsection (g) of the Act are inapplicable to the extent that this system of records is exempted from those subsections of the Act.

The EPA also compiles and maintains the records in the OIG Data Analytics Enterprise for use in civil and administrative investigations and actions. In those cases, the system again is maintained by the Office of Inspector General. 5 U.S.C. 552a(k)(2) states that the head of an agency may promulgate regulations to exempt the system from certain provisions of the Act if the system ''is investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2)'' of 5 U.S.C. 552a. Accordingly, to the extent investigatory records are not covered under the exemptions in subsection (j)(2), the following provisions of the Privacy Act

are exempt pursuant to 5 U.S.C. 552a(k)(2): 5 U.S.C. 552a(c)(3), 5 U.S.C. 552a(d), 5 U.S.C. 552a(e)(1), 5 U.S.C. 552a(e)(4)(G) and (H) and 5 U.S.C. 552a(f)(2) through (5):

(1) From subsection (c)(3) because making available to named individual an accounting of disclosures of records concerning him/her/them could reveal investigative interest on the part of EPA and/or the Department of Justice. This could allow record subjects to impede the investigation, *e.g.,* destroy evidence, intimidate potential witnesses, or flee the area to avoid inquiries or apprehension by law enforcement personnel. More broadly, the application of this provision could reveal the OIG's investigative interests, which could compromise those investigative interests. Further, such a disclosure could reveal the identity of a confidential source and hamper the Agency's investigation.

(2) From subsection (d), which requires an agency to permit an individual to access, contest or request amendment of records pertaining to him/her/them, because the records contained in this system relate to official Federal investigations. Individual access to these records could compromise ongoing investigations, reveal confidential informants and/or sensitive investigative techniques used in particular investigations, or constitute unwarranted invasions of the personal privacy of third parties who are involved in a certain investigation.

(3) From subsection (e)(1), which requires each agency to maintain only such information about an individual as is relevant and necessary to accomplish a purpose of the agency, because in the course of law enforcement investigations information may occasionally be obtained or introduced the accuracy of which is unclear or which is not strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of criminal activity. Moreover, it would impede any investigative process, whether civil or criminal, if it were necessary to assure the relevance, accuracy, timeliness and completeness of all information obtained.

(4) From subsections (e)(4)(G) and (H), which require an agency to publish—in the **Federal Register**—procedures concerning access to records, because no access to these records is available under subsection (d) of the Privacy Act, for the reasons explained above in the discussion of subsection (d).

(5) From subsection (f)(2), (f)(3), (f)(4), and (f)(5), concerning agency rules for obtaining access to records under subsection (d), because this system is exempt from the access and amendment provisions of subsection (d). Since EPA is exempting this system of records from subsection (d) of the Act, concerning access to records, the requirements of subsections (f)(2) through (5) of the Act, concerning agency rules for obtaining access to such records, are inapplicable and are exempted to the extent that this system of records is exempted from subsection (d) of the Act.

The EPA also compiles and maintains the records in the OIG Data Analytics Enterprise, EPA–100, for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information. In those cases, the system again is maintained by the Office of Inspector General. The statute at 5 U.S.C. 552a(k)(5) states that the head of any agency may by rule exempt any system of records within the agency from certain provisions of the Privacy Act, if the system of records is investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence. Accordingly, to the extent any records would disclose source-identifying information, all such information in the OIG Data Analytics Enterprise, EPA–100, are exempt from 5 U.S.C. 552a(c)(3) and 5 U.S.C. 552a(d):

(1) From subsection (c)(3) because making available to named individual an accounting of disclosures of records concerning him/her/them could reveal investigative interest on the part of EPA and/or the Department of Justice. This could allow record subjects to impede the investigation, *e.g.,* destroy evidence, intimidate potential witnesses, or flee the area to avoid inquiries or apprehension by law enforcement personnel. More broadly, the application of this provision could reveal the OIG's investigative interests, which could compromise those investigative interests. Further, such a disclosure could reveal the identity of a confidential source and hamper the Agency's investigation.

(2) From subsection (d), which requires an agency to permit an individual to access, contest or request amendment of records pertaining to him/her/them, because the records contained in this system relate to official Federal investigations. Individual access to these records could compromise ongoing investigations, reveal confidential informants and/or sensitive investigative techniques used in particular investigations, or constitute unwarranted invasions of the personal privacy of third parties who are involved in a certain investigation.

III. Statutory and Executive Orders Reviews

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

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

This action was submitted to the Office of Management and Budget (OMB) for review and reviewed without comment.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This action contains no provisions constituting a collection of information under the PRA.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

E. Executive Order 13132 (Federalism)

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 16

Environmental protection, Administrative practice and procedure, Confidential business information, Government employees, Privacy.

Kimberly Y. Patrick,

Principal Deputy Assistant Administrator, Office of Mission Support.

For the reasons set forth in the preamble, EPA amends 40 CFR part 16 as follows:

PART 16—IMPLEMENTATION OF PRIVACY ACT OF 1974

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552a (as revised).

■ 2. Amend § 16.11 by:
■ a. Revising paragraph (a) and (c)(2);
■ b. Adding paragraph (c)(6); and
■ c. Revising paragraph (d) and the introductory text of paragraph (e).

The revisions and addition read as follows:

§ 16.11 General exemptions.

(a) *Systems of records affected.* (1) EPA–17 Online Criminal Enforcement Activities Network (OCEAN).

(2) EPA–40 Inspector General Enterprise Management System (IGEMS) Investigative Module.

(3) EPA–63 eDiscovery Enterprise Tool Suite.

(4) EPA–79 NEIC Master Tracking System.

(5) EPA–100 OIG Data Analytics Enterprise.

* * * * *

(c) * * *

(2) The Agency's system of records, EPA–40 is maintained by the Office of Inspector General (OIG), an independent component of EPA that performs as its principal function activities pertaining to the enforcement of criminal laws. Authority for the criminal law enforcement activities of the OIG's Office of Investigations is the Inspector General Act of 1978, as amended, 5 U.S.C. 401–424.

* * * * *

(6) The Agency's system of records, EPA–100 system of records is maintained by the Office of Inspector General, an independent component of EPA which performs as its principal function activities pertaining to the enforcement of criminal laws. Authority for the criminal law enforcement activities of the Office of Inspector General is the Inspector General Act of 1978, as amended, 5 U.S.C. 401–424.

(d) *Scope of exemption.* EPA systems of records 17, 40, 63, 79, and 100 are exempted from the following provisions of the PA: 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (2), (3), (4)(G), and (H), (5), and (8); (f)(2) through (5); and (g). To the extent that the exemption for EPA systems of records 17, 40, 63, 79 and 100 claimed under 5 U.S.C. 552a(j)(2) is held to be invalid, then an exemption under 5 U.S.C. 552a(k)(2) is claimed for these systems of records from (c)(3), (d), (e)(1), (e)(4)(G) and (H), and (f)(2) through (5). For Agency's system of records, EPA system 40, an exemption is separately claimed under 5 U.S.C. 552(k)(5) from (c)(3), (d), (e)(1), (e)(4)(G), (4)(H), and (f)(2) through (5). For Agency's system of records, EPA system 100, an exemption is separately claimed under 5. U.S.C. 552(k)(5) from (c)(3) and (d).

(e) *Reasons for exemption.* EPA systems of records 17, 40, 63, 79, and 100 are exempted from the provisions of the PA in paragraph (d) of this section for the following reasons:

* * * * *

■ 3. Amend § 16.12 by revising paragraph (a)(1), the first sentence in paragraph (a)(4)(i), paragraph (a)(4)(iii), the introductory text of paragraph (a)(5), paragraphs (b)(1) and (4), and the introductory text of paragraph (b)(5) to read as follows:

§ 16.12 Specific exemptions.

(a) * * *

(1) *Systems of records affected.* (i) EPA–17 Online Criminal Enforcement Activities Network (OCEAN).

(ii) EPA–21 External Compliance Case Tracking System (EXCATS).

(iii) EPA–30 Inspector General Enterprise Management System (IGEMS) Hotline Module.

(iv) EPA–40 Inspector General Enterprise Management System (IGEMS) Investigative Module.

(v) EPA–63 eDiscovery Enterprise Tool Suite.

(vi) EPA–79 NEIC Master Tracking System.

(vii) EPA–100 OIG Data Analytics Enterprise.

* * * * *

(4) * * *

(i) EPA systems of records 17, 30, 40, 63, 79, and 100 are exempted from the following provisions of the PA, subject to the limitations set forth in 5 U.S.C. 552a(k)(2): 5 U.S.C. 552a(c)(3); (d); (e)(1), (4)(G) and (4)(H); and (f)(2) through (5). * * *

* * * * *

(iii) EPA–17 Online Criminal Enforcement Activities Network (OCEAN), EPA–40 Inspector General Enterprise Management System (IGEMS) Investigative Module, EPA–79 NEIC Master Tracking System, and EPA–100 OIG Data Analytics Enterprise are exempted under 5 U.S.C. 552a(j)(2), and these systems are exempted under 5 U.S.C. 552a(k)(2) only to the extent that the (j)(2) exemption is held to be invalid.

(5) *Reasons for exemption.* EPA systems of records 17, 21, 30, 40, 63, 79, and 100 are exempted from the provisions of the PA in paragraph (a)(4) of this section for the following reasons:

* * * * *

(b) * * *

(1) *Systems of records affected.* (i) EPA 36 Research Grant, Cooperative Agreement, and Fellowship Application Files.

(ii) EPA 40 Inspector General Enterprise Management System (IGEMS) Investigative Module.

(iii) EPA 100 OIG Data Analytics Enterprise.

* * * * *

(4) *Scope of exemption.* (i) EPA 36 and 100 are exempted from 5 U.S.C. 552a(c)(3) and (d). EPA 40 is exempted from the following provisions of the PA,

subject to the limitations of 5 U.S.C. 552a(k)(5); 5 U.S.C. 552a(c)(3); (d); (e)(1), (4)(H); and (f)(2) through (5).

(ii) To the extent that records in EPA 40 and 100 reveal a violation or potential violation of law, then an exemption under 5 U.S.C. 552a(k)(2) is also claimed for these records. EPA 40 and 100 are also exempt under 5 U.S.C. 552a(j)(2).

(5) *Reasons for exemption.* EPA 36, 40, and 100 are exempted from the above provisions of the PA for the following reasons:

* * * * *

[FR Doc. 2023–24233 Filed 11–7–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 1074

[EPA–HQ–OAR–2022–0985; FRL–8952.1–01–OAR]

RIN 2060–AW12

Locomotives and Locomotive Engines; Preemption of State and Local Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing revisions to its regulations addressing preemption of State and local regulation of locomotives and engines used in locomotives. This rule implements a policy change to no longer categorically preempt certain State regulations of non-new locomotives and engines, aligning with the plain text of the Clean Air Act (CAA), and better achieving the legislative intent of providing for exclusive Federal regulation of new locomotives and new locomotive engines while preserving the ability of California and other States to adopt and enforce certain State standards regulating non-new locomotives and engines.

DATES: This final rule is effective on December 8, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2022–0985. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) 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 electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Brian Nelson, Assessment and Standards Division, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4278; email address: *nelson.brian@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

Does this action apply to me?

This action does not directly apply to any regulated industry classified by the North American Industry Classification System (NAICS) Association.[1] This action relates to State and local governments. The revisions we are finalizing do not impose any requirements that State and local governments must meet, but rather implement the Clean Air Act preemption provisions for locomotives. To determine whether your entity could be impacted by this action, you should carefully examine the applicability criteria found in 40 CFR part 1074. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

What action is the Agency taking?

The Environmental Protection Agency (EPA) is finalizing revisions to its regulations addressing preemption of State regulation of new locomotives and new engines used in locomotives, to align with language in the Clean Air Act.

What is the Agency's authority for taking this action?

Clean Air Act (CAA) section 209(e)(2)(B), 42 U.S.C. 7543(e)(2)(B), requires EPA to promulgate regulations implementing section 209(e) of the Act. CAA section 209(e)(1) addresses the prohibition of State standards regarding certain classes of new nonroad engines or new nonroad vehicles including new locomotives and new engines used in locomotives.[2] CAA section 209(e)(2)(A) specifies the criteria relevant to EPA's evaluation of California authorization requests (requests for a waiver of CAA preemption) for standards relating to the control of emissions from nonroad engines or nonroad vehicles other than those prohibited under section 209(e)(1). EPA's regulations implementing these provisions for locomotives and locomotive engines were first adopted in 1998 at 40 CFR part 85 and transcribed in 2008 at 40 CFR part 1074.[3]

I. Summary

As part of its 1998 rule finalizing Emission Standards for Locomotives and Locomotive Engines at 40 CFR part 92, which applied to new locomotives and new engines used in locomotives, EPA also adopted regulations in 40 CFR part 85 defining a broad preemption of certain State and local controls of new or other locomotives and engines used in locomotives, which we determined to be appropriate based on our understanding of the information available at the time. Recently, there has been interest in obtaining greater emissions reductions from the locomotive sector, including possibly adopting programs to achieve greater emission reductions from non-new locomotives that are not required by EPA's emission standards for new locomotives and engines under CAA section 213(a)(5).[4] On April 27, 2023, EPA published a notice of proposed rulemaking which, among other things, proposed revisions to our locomotive preemption regulations.[5] Specifically, we proposed to delete 40 CFR 1074.12(b), which preempted the State control of non-new locomotives for certain categories of State control measures for a period of 133 percent of the useful life of a new locomotive or engine,[6] along with conforming edits.

[1] NAICS Association. NAICS & SIC Identification Tools. Available online: *https://www.naics.com/search.*

[2] Section 209(e) pertains to the inability of State and political subdivisions to adopt and enforce standards and other requirements for certain nonroad engines and nonroad vehicles. EPA's reference to ''State'' herein includes political subdivisions unless otherwise noted.

[3] *See* Emission Standards for Locomotives and Locomotive Engines, Final Rule, 63 FR 18978, 18994 (April 16, 1998). *See also,* Control of Emissions From Nonroad Spark-Ignition Engines and Equipment, 73 FR 59034 (Oct. 8, 2008); *See also* Control of Air Pollution: Emission Standards for New Nonroad Compression-Ignition Engines at or Above 37 Kilowatts; Preemption of State Regulation for Nonroad Engine and Vehicle Standards; Amendments to Rules, 62 FR 67733, 67734–67735 (December 30, 1997). *See also* Air Pollution Control; Preemption of State Regulation for Nonroad Engine and Vehicle Standards, July 20, 1994 (59 FR 36969).

[4] Throughout this document, references to the regulation of locomotives generally refer the regulation of both locomotives and engines used in locomotives.

[5] *See,* Greenhouse Gas Emissions Standards for Heavy-Duty Vehicles-Phase 3; Proposed Rule, April 27, 2023, 88 FR 25926.

[6] Including but not limited to emission standards, mandatory fleet average standards, certification requirements, retrofit and aftermarket equipment

Because this proposal was included in EPA's larger Phase 3 Heavy-Duty Greenhouse Gas notice of proposed rulemaking, it shared and continues to share a docket ID number with that proposal. We have decided to finalize this locomotive preemption portion of the proposal as a separate final rule, while preserving our discretion to take separate final action on all other aspects of the proposal at a future date.

In this final rule, EPA is adopting the revisions to part 1074 as proposed and with no further adjustments. We received overwhelming support from commenters, as well as a few adverse comments. In this preamble, we have highlighted only a few of those comments to explain the basis of EPA's final locomotive preemption regulation. EPA has prepared a comprehensive Response to Comments document, in which we respond to all significant comments we received during the public comment period on the issues addressed in this rule.[7]

II. Background

The CAA Amendments of 1990 called on EPA to adopt emission standards for new locomotives and new locomotive engines that achieve the greatest degree of emission reduction achievable through the application of technology which EPA determines will be available for the locomotives or engines, giving appropriate consideration to the cost of applying such technology within the period of time available to manufacturers and to associated noise, energy, and safety factors. CAA section 213(a)(5), 42 U.S.C. 7547(a)(5).[8] These 1990 amendments also added CAA section 209(e) which sets out provisions that prohibit States or any political subdivision thereof from regulating certain nonroad engines or vehicles, provisions that set forth the requirement that EPA must authorize California standards and other requirements relating to the control of emissions from other nonroad vehicles and engines unless specified criteria are found by EPA, and provisions that set forth how States other than California can adopt California nonroad vehicle or engine standards if certain criteria are met. Section 209(e)(2) directed the Administrator of EPA to issue regulations to implement section 209(e).

In April of 1998, EPA adopted its first-ever regulations addressing air pollutant emissions from new locomotives and new locomotive engines (including freshly built and remanufactured) under CAA section 213(a)(5), 42 U.S.C. 7547(a)(5).[9] As part of the 1998 final rule, EPA also promulgated regulations designed to codify the nonroad preemption provisions of section 209(e)(1)(B) to clarify the prohibition of any State standard or other requirement relating to the control of emissions from new locomotives or new engines used in locomotives.[10] EPA's rule included a provision that set a period equivalent in length to 133 percent of the regulatory useful life of a new locomotive or engine during which certain categories of control measures are preempted, whether applicable to new or other locomotives or locomotive engines.[11] EPA also adopted regulations to implement the CAA provisions allowing California to request authorization for other State requirements on non-new locomotives and engines used in locomotives not otherwise prohibited.[12]

As we explained in the April 27, 2023, proposed rule to amend part 1074, recent fleet profile data shows that the in-service locomotive fleet continues to be dominated by Tier 2 and earlier locomotives subject to EPA's less stringent emission standards.[13] According to data supporting EPA's 2020 National Emission Inventory, there are 16,787 locomotives in the Class I line-haul fleet.[14] Of these, about 26 percent are Tier 3 or Tier 4 locomotives subject to more stringent emission standards.[15] The other 74 percent are Tier 2 or earlier locomotives, broken down as follows: About 62 percent are remanufactured to the revised remanufacture standards adopted in 2008; 11 percent have not been remanufactured and continue to have the higher emissions of their original certification tier; and a small number, about 1 percent, are unregulated (pre-1973) locomotives. The Class II and III line-haul fleet consists of 3,447 locomotives. Of these, about seven percent are Tier 3 or 4 locomotives. The other 93 percent are Tier 2 or earlier, broken down as follows: About 39 percent of the locomotives are unregulated (pre-1973); 48 percent are Tier 0; and the other six percent are Tier 1 or Tier 2.

In the April 27, 2023, proposal, we noted that there is interest from entities who must develop State implementation plans (SIPs) demonstrating attainment of national ambient air quality standards (NAAQS) in obtaining greater emissions reductions from the locomotive sector, including possibly adopting programs to achieve greater emission reductions from non-new locomotives that are not required by EPA's emissions standards for new locomotives and engines under CAA section 213(a)(5). This interest is related to the large share of older locomotives in the Class I, II, and III railroad fleets and their emissions contribution to ambient concentrations of air pollution that may violate the ozone and particulate matter NAAQS.

Nevertheless, the action taken here to revise our locomotive preemption regulations does not achieve reductions of such emissions. Rather, by aligning with the CAA, it may provide latitude for the development of State approaches to addressing emissions from non-new locomotives and non-new engines used in locomotives that are not required to be reduced by EPA's emissions standards for new locomotives and engines under CAA section 213(a)(5). In enacting the 1990 CAA amendments and section 209(e) for nonroad equipment including non-new locomotives, Congress recognized the unique role and air quality concerns of California and clearly envisioned the

requirements, and non-Federal in-use testing requirements.

[7] Response to Comments: Revisions to Preemption Regulations for Locomotives and Locomotive Engines, EPA–420–R–23–032, available at *https://www.epa.gov/regulations-emissions-vehicles-and-engines/revisions-preemption-regulations-locomotives-and.*

[8] EPA provides this discussion of the Federal locomotive requirements under the CAA for background purposes only. In this rulemaking, EPA did not reopen the Federal locomotive requirements, and any comments on such are beyond the scope of the action and will not be addressed here.

[9] Emission Standards for Locomotives and Locomotive Engines, 63 FR 18978 (April 16, 1998), codified at 40 CFR parts 85, 89 and 92. EPA's locomotive emission regulations were later moved to 40 CFR part 1033. The preemption regulations were later transcribed at 40 CFR 1074.12; see 73 FR 59034 (Oct. 8, 2008).

[10] EPA had previously set out the other nonroad preemption provisions (except for locomotives) in 1994 (59 FR 36969) and revised them in 1997 (62 FR 67733).

[11] See Note 6.

[12] To avoid confusion of the term ''used'' sometimes meaning ''placed or mounted,'' we employ the term ''non-new'' to describe engines that do not meet the definition of ''new'' in § 1074.5.

[13] 2020 National Emissions Inventory Locomotive Methodology Prepared for U.S. Environmental Protection Agency by Eastern Research Group, Inc. (May 19, 2022). *https://gaftp.epa.gov/air/nei/2020/doc/supporting_data/nonpoint/Rail/2020_NEI_Rail_062722.pdf.*

[14] The current classification of railroads adopted by the Surface Transportation Board (STB) in 2021 is based on annual carrier operating revenue, as follows: Class I railroads, greater than $943.9 million; Class II railroads, $42.4 to $943.9 million; Class III railroads less than $42.4 million. See 49 CFR part 1201 (1–1 Classification of Carriers).

[15] EPA took action to set additional emission standards for new locomotives and engines in 2008; see final rule published at 73 FR 37096 (June 30, 2008), codified at 40 CFR part 1033, Control of Emissions of Air Pollution From Locomotive Engines and Marine Compression-Ignition Engines Less Than 30 Liters per Cylinder.

potential for California to regulate non-new locomotives. This is plainly shown by the combination of statutory provisions—at CAA sections 213(a)(5), 209(e)(1)(B), and 209(e)(2)(A)—that clearly show that although EPA has exclusive authority to regulate emissions from new locomotives and engines and certain other new nonroad engines and vehicles, California retained the ability to seek authorization to regulate ''other nonroad engines or vehicles,'' including those that are non-new locomotives and locomotive engines. The purpose of EPA's revisions is to effectuate this Congressional intent and the language of the CAA whereby control measures for non-new locomotives must be able to obtain authorization so long as they satisfy the criteria in section 209(e) of the Act.

III. Regulatory Changes in This Final Rule

EPA is finalizing several revisions in 40 CFR part 1074, including §§ 1074.10, 1074.12, and 1074.101, to align EPA's regulations with CAA section 209(e).

In 40 CFR 1074.10, ''Scope of preemption,'' we are revising § 1074.10(b) to contain text that is currently located in § 1074.12(a) and shifting the current text of § 1074.10(b) into a new § 1074.10(c). This is solely a housekeeping measure and does not revise the text contained in current § 1074.12(a); it is only a transcription.

We are deleting 40 CFR 1074.12, ''Scope of preemption-specific provisions for locomotives and locomotive engines,'' in its entirety. The previous text at 40 CFR 1074.12(b) preempted the State control of non-new locomotives for certain categories of State control measures for a period of 133 percent of useful life of a new locomotive or engine.[16] We believe the removal of the explicit period of preemption in § 1074.12(b) as well as the listed categories of State control measures will reflect that not all State regulations addressing non-new locomotives were intended by Congress to be preempted without the possibility of obtaining a waiver of preemption and will align the requirements and effects of the regulation with the plain language of the CAA.

In 40 CFR 1074.101, ''Procedures for California nonroad authorization requests,'' we are finalizing a minor housekeeping edit to paragraph (a) of this section, to refer to the relocated text in § 1074.10(b) that is being moved out of § 1074.12.

[16] See Note 6.

IV. Comments Received and Responses

We received several comments expressing concerns about emissions from non-new locomotives and their impact on communities, especially for areas located along high traffic rail lines and/or in communities with environmental justice concerns. We acknowledge these concerns about the harmful impacts of locomotive emissions on these communities. We received many comments supporting the removal of § 1074.12(b), including from the Environmental Defense Fund, the Moving Forward Network, and the National Association of Clean Air Agencies. We are finalizing the revisions as proposed.

Comments from industry on this topic include concerns from Wabtec that EPA's proposed revisions could take away the stability and predictability of a Federally-uniform regulatory program for new locomotives and engines.[17] We acknowledge the concern, but it is misplaced. Only EPA has the authority to promulgate standards and requirements that apply to new locomotives and new engines used in locomotives, and this rule does nothing to change that exclusive authority. California may not adopt and enforce standards or requirements that apply to new locomotives or new engines used in locomotives, as is plainly prohibited by section 209(e)(1)(B). As EPA noted in the proposal, section 209(e)(2)(A) of the Act requires EPA to authorize California's emission standards for certain nonroad engines and vehicles, including for non-new locomotives and non-new engines used in locomotives, so long as California meets the requirements of that provision. Further, section 209(e)(2)(B) also allows certain States to adopt California's standards so long as they meet the statutory criteria. EPA's final rule aligns the regulation with these clear statutory requirements.

In any case, we do not believe that our action improperly diminishes the regulatory stability referred to by the commenter. The underlying CAA preemption language protects manufacturers from having to juggle compliance with conflicting State and Federal regulations of new locomotives, and only EPA's regulations promulgated under CAA section 213(a)(5) can impose compliance requirements on new locomotives and new engines used in locomotives. There is no possibility, under either the CAA or as a result of EPA's amended preemption regulations, for California or any other State to adopt and enforce different standards or other requirements that would apply to new locomotives or new engines used in locomotives. In addition, EPA's authorization process insulates manufacturers from State-level rules that could significantly affect the design and manufacture of new locomotives or new locomotive engines. Under this final rule, EPA remains obliged to adhere to the statutory authorization criteria in CAA section 209(e)(2). EPA also intends to consider the reasoning of *Allway Taxi* in reviewing any California rules submitted to EPA for authorization pursuant to 40 CFR 1074.101 through 1074.105.[18] A comment received from the Association of American Railroads supports this point, emphasizing that the removal of the categorical preemption of certain types of State regulations that EPA has, to date, deemed likely to significantly affect the design and manufacture of new locomotives or new locomotive engines, does not change the underlying statutory limitation against which EPA would evaluate a future request.[19] Specifically, the statutory limitation referenced in that comment is the one at CAA section 209(e)(2)(A), which requires the Administrator, after notice and opportunity for public hearing, to authorize California to adopt and enforce standards and other requirements relating to the control of emissions from such nonroad vehicles or engines not preempted by CAA section 209(e)(1) if California

[17] See comment from Westinghouse Air Brake Technologies Corporation at EPA–HQ–OAR–2022–0985–1580–A1, pp. 8–9.

[18] EPA notes, as set out in the notice of proposed rulemaking, that in implementing this authorization authority it also expects to continue to consider the reasoning of *Allway Taxi* v. *City of New York,* 340 F. Supp. 1120 (S.D.N.Y 1972), *aff 'd,* 468 F.2d 624 (2d Cir. 1972): ''We do not say that a state or locality is free to impose its own emission control standards the moment after a new car is bought and registered. That would be an obvious circumvention of the Clean Air Act and would defeat the congressional purpose of preventing obstruction to interstate commerce. The preemption sections, however, do not preclude a state or locality from imposing its own exhaust emission control standards upon the resale or reregistration of the automobile. Nor do they preclude a locality from setting its own standards for the licensing of vehicles for commercial use within that locality. Such regulations would cause only minimal interference with interstate commerce, since they would be directed primarily to intrastate activities and the burden of compliance would be on individual owners and not on manufacturers and distributors.'' See also, *Engine Manufacturers Ass'n* v. *EPA,* 88 F.3d 1075, 1086 & n. 39 (D.C. Cir. 1996) (endorsing *Allway Taxi* rationale); *Engine Manufacturers Ass'n* v. *South Coast Air Quality Management Dist.,* 541 U.S. 246, 254 (2004) (holding that Section 209(a) preempts certain State rules that would pressure manufacturers to change the design of new engines even when ''not enforced through manufacturer-directed regulation'').

[19] See comment from the Association of American Railroads & American Short Line and Regional Railroad Association at EPA–HQ–OAR–2022–0985–1492–A1, p. 4–5.

determines that California standards will be, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. Further, 209(e)(2)(A) states EPA shall not grant such authorization if it finds that (1) the protectiveness determination of California is arbitrary and capricious; (2) California does not need such standards to meet compelling and extraordinary conditions; or (3) California standards and accompanying enforcement procedures are not consistent with CAA section 209.

We also received an adverse comment on this topic from the American Free Enterprise Chamber of Commerce, claiming that the proposal did not provide a compelling policy reason for deviating from the previous approach to Federal preemption of State regulation of locomotives and engines, whether new or other locomotives and engines.[20] While EPA is making a policy change to no longer categorically preempt State regulation of non-new locomotives and engines, this final rule aligns with the plain text of the CAA, is well supported by the factual record including developments since the 1998 final rule, and better achieves the legislative intent of providing for exclusive Federal regulation of new locomotives and new locomotive engines while preserving the ability of obtaining a waiver of preemption for regulating non-new locomotives and engines.[21] As we explain in section II of this document, the final rule aligns EPA's regulations with the clear text of sections 213(a)(5), 209(e)(1)(B) and 209(e)(2)(A) of the CAA. While the agency has discretion to establish further criteria for authorizations by regulation beyond what are specified in the statute, as we did in the 1998 rule, the statute does not require this result.[22] Rather, the statute at section 209(e)(2) establishes a process where EPA authorizes, on a case-by-case basis, certain California nonroad engine and vehicle standards, including those applicable to non-new locomotives, so long as they satisfy the criteria in section 209(e)(2)(A). The final rule faithfully implements this statutory process for non-new locomotives and engines.

Moreover, EPA is making new factual findings that support the change in policy. As explained in the April 27, 2023, proposal and further explained in the Response to Comments document, we have identified certain developments that indicate that the categorical exclusion of some of the specified standards and requirements for 133 percent of the useful life period of new locomotives or engines is no longer in all cases appropriate. We identified illustrative emissions control technologies which have been voluntarily applied to non-new locomotives and prima facie would not appear to significantly affect the design or manufacture of new locomotives.[23] In light of the changed factual record, we believe that the 1998 rule's categorical bar on certain types of controls for non-new locomotives is no longer appropriate, and that instead, the agency ought to evaluate on a case-by-case basis whether to authorize standards involving such controls for non-new locomotives.

Finally, as we explained in the proposal, this rule better achieves Congress's intent to differentiate between Federal regulation of new locomotives and possible State regulation of non-new locomotives. Although it is clear from the plain language of CAA sections 213(a)(5) and 209(e)(1)(B) that only EPA is to regulate new locomotives and engines, section 209(e)(2) contemplates that California may adopt certain standards for non-new locomotives to address its air quality problems, and that other States may follow California's lead. Throughout section 209, Congress contemplated that authorizing California's ''pioneering'' regulatory efforts would create a State-level laboratory for innovation, driving experimentation in ''new control systems and designs'' that would benefit the nation as a whole.[24] Although Congress, in section 209(e)(1)(B), precluded California's ability to regulate new locomotives and engines, the 1998 final rule's categorical bar on certain controls whether applicable to new or other locomotives and engines may have also precluded California and other States from exploring innovative local programs to address pollution from non-new locomotives and in turn achieving the potential emissions reductions of such programs—programs that EPA could not include in its emission standards under section 213(a)(5) that apply only to new locomotives and engines. This final rule ensures that such programs for non-new locomotives and engines may be authorized so long as they meet the statutory authorization criteria and in turn yield benefits for public health and the environment.

This action does not change the scope of preemption of State regulation of new locomotives and new engines used by locomotives, which is established by CAA section 209(e)(1). EPA agrees with the commenter that we are making a policy change with regard to whether to evaluate State regulation of non-new locomotives and engines at all, but we are not changing any of the criteria for evaluating authorization requests. On review of the extension of the preemption provisions adopted in 1998 as reaching ''other locomotives or locomotive engines,'' in addition to those that are ''new,'' without preserving the authority under CAA section 209(e)(2) to consider for authorization State regulation of the types of standards or requirements listed at § 1074.12(b), we now view the provisions at § 1074.12(b) as unnecessarily restricting such consideration beyond what the statute requires at CAA section 209(e)(1)(B). Moreover, as explained in the April 27, 2023, proposal, we have identified certain developments that indicate that the categorial exclusion of some of the specified standards and requirements for the 133 percent of the useful life period of new locomotives or engines is no longer in all cases appropriate. Consequently, we believe it is important that our regulations not unnecessarily constrain EPA's future evaluation of a State request for authorization to regulate non-new locomotives and non-new engines used in locomotives under § 1074.101. Indeed, one reason for this revision is to eliminate any such constraint that is apparent in current 40 CFR 1074.12(b).

EPA notes that concerns may exist related to authorization requests that include forms of State controls that could significantly affect the design or manufacture of a new locomotive or new engines used in locomotives. As explained in the April 27, 2023, proposal, EPA recognizes that significant advances in technology have occurred in the intervening years since 1998, along with innovative forms of regulations. Any State authorization application that includes locomotive emission regulations would be subject to consideration of whether such regulations significantly affect the design or manufacture of a new

[20] See comment from the American Free Enterprise Chamber of Commerce at EPA–HQ–OAR–2022–0985–1660–A1, p. 70.

[21] Under governing caselaw, an agency may change policies so long as it recognizes the change and articulates a good reason for it. To the extent the commenter believes that some heightened standard applies, such that a ''compelling'' justification is required, that argument has not been raised with reasonable specificity as required by CAA section 307(d)(7)(B), and in any event is inconsistent with the caselaw. See *F.C.C.* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 514–15 (2009).

[22] *NLRB* v. *Bell Aerospace Co.,* 416 U.S. 267, 294 (1974). (''the choice between rulemaking and adjudication lies in the first instance within the [agency's] discretion'').

[23] 88 FR 26094–95.

[24] S. Rep. No. 90–403, at 33.

locomotive or new engine used in a locomotive to the extent such is prohibited by section 209(e)(1)(B). EPA will evaluate any such application on a case-by-case basis to determine if the controls may be authorized under section 209(e)(2)(A) and 40 CFR 1074.101 through 1074.110.

Our proposed rule to revise the preemption language did not reopen any aspect of the Federal regulatory program for new locomotives and new engines used in locomotives set forth at 40 CFR part 1033. Consequently, none of the changes to our preemption regulations will have any impact on EPA's regulation of new locomotives or engines used in locomotives (including freshly built and remanufactured) under 40 CFR part 1033. There are no potential costs or benefits to regulated entities of any size as a result of these amendments to our preemption regulations. Although several commenters on our proposed rule urged EPA to take steps toward more stringent Federal emissions standards for locomotives, those comments are beyond the scope of this rulemaking as EPA did not propose or seek comments on any amendments to EPA's Federal regulations to reduce the air emissions from new locomotives or new engines used in locomotives. EPA reserves its discretion to revisit the part 1033 regulations separately.

V. Statutory and Executive Order Reviews

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

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because it does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This rule simply revises EPA's regulations to align with section 209 of the Clean Air Act and to preserve for separate future adjudications under CAA section 209(e)(2) whether a State rule addressing non-new locomotives or engines would impermissibly relate to the control of emissions from new locomotives or engines under section 209(e)(1). As a result of this action alone there are no potential impacts to railroads, of any size.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action has federalism implications because these revisions to part 1074 involve existing regulations that preempt State law under CAA section 209(e). In this rule, EPA is revising our locomotive preemption regulations to align with language Congress provided in section 209(e)(1)(B) and the congressional directive to EPA to implement the prohibition of State regulation of new locomotives and new engines used in locomotives while ensuring that States are not impeded from adopting standards and other requirements relating to the control of emissions as allowed by the CAA to address the contribution of air pollutant emissions from non-new locomotives and non-new engines used in locomotives to their air quality issues. EPA consulted with representatives of various State and local governments in developing this rule. Our outreach to State and local governments has satisfied Executive Order 13132. EPA solicited and received comments on this revision from many State and local officials. Specifically, we received a letter with strongly supportive comments signed by officials from 12 States, as well as supportive comments from the Ozone Transport Commission, National Association of Clean Air Agencies (NACAA), and Northeast States for Coordinated Air Use Management (NESCAUM).

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

This action does not have Tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action. This action does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. In the development of the proposed Greenhouse Gas Emissions Standards for Heavy-Duty Vehicles—Phase 3 and this final rule, EPA engaged with our Tribal stakeholders. We did so primarily by offering government-to-government consultation upon request but also offered information sessions and presentations to Tribal audiences.

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

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order.

This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since the action does not concern human health, EPA's Policy on Children's Health also does not apply.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that this type of action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to potentially disproportionate and adverse effects on communities with environmental justice concerns. This rule does not achieve reductions of locomotive emissions.

Although this action does not concern human health or environmental conditions, EPA recognizes that locomotive emissions are an environmental justice concern, and we promoted meaningful involvement in

several ways. For example, we contacted individuals in environmental justice groups about the proposal and provided information about the public hearings and the comment period; provided information on our website in both Spanish and English; and provided Spanish translation during the public hearings. We received and considered comments from those with environmental justice concerns, as described in the Response to Comments document.[25]

K. Congressional Review Act

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

VI. Statutory Authority and Legal Provisions

Statutory authority for these revisions to our preemption regulations is found in CAA section 209(e)(2)(B), 42 U.S.C. 7543(e)(2)(B), which requires EPA to promulgate regulations implementing CAA section 209(e), which in turn addresses the prohibition of State standards regarding certain classes of new nonroad engines or new nonroad vehicles including new locomotives and new engines used in locomotives, as well as EPA's authorization criteria for certain California standards for other nonroad engines or nonroad vehicles.

VII. Judicial Review and Administrative Reconsideration

Under CAA section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by January 8, 2024. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements. Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460. Under CAA section 307(b)(1), the filing of a petition for reconsideration shall not affect the finality of the rule for purposes of judicial review nor extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of the rule.

[25] See Note 7.

List of Subjects in 40 CFR Part 1074

Environmental protection, Administrative practice and procedure, Air pollution control, Locomotives, Nonroad engines, Scope of preemption.

Michael S. Regan,

Administrator.

For the reasons set out in the preamble, EPA amends title 40, chapter I of the Code of Federal Regulations as set forth below.

PART 1074—PREEMPTION OF STATE STANDARDS AND PROCEDURES FOR WAIVER OF FEDERAL PREEMPTION FOR NONROAD ENGINES AND NONROAD VEHICLES

■ 1. The authority citation for part 1074 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart A—Applicability and General Provisions

■ 2. Amend § 1074.10 by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 1074.10 Scope of preemption.

* * * * *

(b) States and localities are preempted from adopting or enforcing standards or other requirements relating to the control of emissions from new locomotives and new engines used in locomotives.

(c) For nonroad engines or vehicles other than those described in paragraphs (a) and (b) of this section, States and localities are preempted from enforcing any standards or other requirements relating to control of emissions from nonroad engines or vehicles except as provided in subpart B of this part.

§ 1074.12 [Removed]

■ 3. Remove § 1074.12.

Subpart B—Procedures for Authorization

■ 4. Amend § 1074.101 by revising paragraph (a) to read as follows:

§ 1074.101 Procedures for California nonroad authorization requests.

(a) California must request authorization from the Administrator to enforce its adopted standards and other requirements relating to control of emissions from nonroad engines or vehicles that are not preempted by § 1074.10(a) or (b). The request must include the record on which the State rulemaking was based.

* * * * *

[FR Doc. 2023–24513 Filed 11–7–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 23–296; RM–11964; DA 23–1030; FR ID 183180]

Television Broadcasting Services Des Moines, Iowa

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Video Division, Media Bureau (Bureau) has before it a notice of proposed rulemaking issued in response to a petition for rulemaking filed by Iowa Public Broadcasting Board (Petitioner), the licensee of noncommercial educational television PBS member station KDIN–TV (KDIN–TV or Station), channel *11, Des Moines, Iowa. The Petitioner has requested the substitution of channel *34 in place of channel *11 at Des Moines in the Table of TV Allotments, and requested that we delete vacant channel *34, Ames, Iowa (Ames) and substitute it with the allotment of vacant channel *21 to Ames. Petitioner filed comments in support of the petition, as required by the Commission's rules (rules), reaffirming its commitment to apply for channel *34.

DATES: Effective November 8, 2023.

FOR FURTHER INFORMATION CONTACT: Emily Harrison, Media Bureau, at (202) 418–1665 or *Emily.Harrison@fcc.gov*.

SUPPLEMENTARY INFORMATION: The proposed rule was published at 88 FR 60611 on September 5, 2023. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel *34. No other comments were received.

The Bureau believes the public interest would be served by substituting channel *34 for channel *11 at Des Moines. Petitioner asserts that the channel substitution from a VHF to UHF channel would serve the public interest by resolving viewer reception challenges and significantly improving the Station's over-the-air service to the viewers in its existing service area. Petitioner includes with its Petition a number of viewer complaints highlighting current reception problems. Petitioner states that the Commission has recognized that VHF channels pose challenges for their use in providing digital television service, including propagation characteristics that allow undesired signals and noise to be receivable at relatively far distances and large variability in the performance of indoor antennas available to viewers, with most antennas performing very poorly on high VHF channels. An engineering statement provided by the Petitioner confirms that the proposed channel *34 contour would provide full principal community coverage to Des Moines. The proposed move from channel *11 to channel *34 is also predicted not to create a loss of service to any viewers, and will increase the area covered while serving the population with higher signal levels, according to the engineering statement. Petitioner acknowledges that the proposed channel substitution would not meet the distance separation requirements regarding the vacant channel *34 allotment at Ames. As a result, Petitioner requests that simultaneously with the substitution of channel *34 at Des Moines, we delete the vacant channel *34 allotment at Ames and substitute it with the allotment of vacant channel *21 to Ames. As stated in its supplemental engineering statement, the proposed channel *21 is described as meeting the distance criteria found in § 73.623(d) of the rules, and an analysis using the Commission's *TVStudy* software is provided showing no interference to any other station or allotment.

This is a synopsis of the Commission's *Report and Order,* MB Docket No. 23–296; RM–11964; DA 23–1030, adopted November 1, 2023, and released November 1, 2023. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

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

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

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

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

PART 73—RADIO BROADCAST SERVICES

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

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

■ 2. In § 73.622(j), amend the Table of TV Allotments, under ''Iowa,'' by revising the entries for ''Ames'' and ''Des Moines'' to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(j) * * *

Community	Channel No.
* * * * *	
Iowa	
Ames	5, *21, 23
* * * * *	
Des Moines	8, 13, 16, 19, *34
* * * * *	

[FR Doc. 2023–24652 Filed 11–7–23; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 385

[Docket No. FMCSA–2023–0122]

RIN 2126–AC61

Incorporation by Reference; North American Standard Out-of-Service Criteria; Hazardous Materials Safety Permits

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FMCSA amends its Hazardous Materials Safety Permit (HMSP) regulations to incorporate by reference the updated Commercial Vehicle Safety Alliance (CVSA) handbook containing inspection procedures and out-of-service criteria (OOSC) for inspections of shipments of transuranic waste and highway route-controlled quantities (HRCQs) of radioactive material (RAM). The OOSC provide enforcement personnel nationwide, including FMCSA's State partners, with uniform enforcement tolerances for inspections. Currently, the regulations reference the April 1, 2022, edition of the handbook. Through this rule, FMCSA incorporates by reference the April 1, 2023, edition.

DATES: Effective December 8, 2023. The incorporation by reference of the material described in the rule is approved by the Director of the Federal Register as of December 8, 2023.

FOR FURTHER INFORMATION CONTACT: Mr. José Cestero, Vehicle and Roadside Operations Division, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–5541, *jose.cestero@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: FMCSA organizes this final rule as follows:

I. Availability of Rulemaking Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2023-0122/document* and choose the document to review. To view comments, click this final rule, then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations at U.S. Department of Transportation 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Executive Summary

This final rule updates an incorporation by reference found at 49 CFR 385.4(b)(1) and referenced at § 385.415(b). The provision at § 385.4(b)(1) currently references the April 1, 2022, edition of CVSA's handbook titled ''North American Standard Out-of-Service Criteria and Level VI Inspection Procedures and Out-of-Service Criteria for Commercial Highway Vehicles Transporting Transuranics and Highway Route Controlled Quantities of Radioactive Materials as defined in 49 CFR part 173.403.'' The CVSA handbook contains inspection procedures and OOSC for inspections of shipments of transuranic waste and HRCQs of RAM. The OOSC, while not regulations, provide enforcement personnel nationwide, including FMCSA's State partners, with uniform enforcement tolerances for inspections. The material is available, and will continue to be available, for inspection at the FMCSA, Office of Safety, 1200 New Jersey Avenue SE, Washington, DC 20590 (Attention: Chief, Compliance Division) at (202) 366–1812. The document may be purchased from the Commercial Vehicle Safety Alliance, 6303 Ivy Lane, Suite 310, Greenbelt, MD 20770, (301) 830–6143, *www.cvsa.org.*

Nine updates distinguish the April 1, 2023, handbook edition from the 2022 edition. The updates are all described in detail in the July 24, 2023, notice of proposed rulemaking (NPRM) for this rule (88 FR 47437). The incorporation by reference of the 2023 edition does not impose new regulatory requirements.

III. Abbreviations

CDL Commercial Driver's License
CFR Code of Federal Regulations
CVSA Commercial Vehicle Safety Alliance
DOT Department of Transportation
FMCSA Federal Motor Carrier Safety Administration
FMCSRs Federal Motor Carrier Safety Regulations
FR Federal Register
HMSP Hazardous Materials Safety Permit
HRCQs Highway route-controlled quantities
MCMIS Motor Carrier Management Information System
OOS Out-of-Service
OOSC Out-of-Service Criteria
RAM Radioactive material
RFA Regulatory Flexibility Act
UMRA The Unfunded Mandates Reform Act of 1995
U.S.C. United States Code

IV. Legal Basis for the Rulemaking

Congress has enacted several statutory provisions to ensure the safe transportation of hazardous materials in interstate commerce. Specifically, in provisions codified at 49 U.S.C. 5105(d), relating to inspections of motor vehicles carrying certain hazardous material, and 49 U.S.C. 5109, relating to motor carrier safety permits (hereinafter ''HMSPs''), the Secretary of Transportation is required to promulgate regulations as part of a comprehensive safety program on HMSPs. The FMCSA Administrator has been delegated authority under 49 U.S.C. 113(f) and 49 Code of Federal Regulations (CFR) 1.87(d)(2) to carry out the functions vested in the Secretary of Transportation related to HMSPs. Consistent with that authority, FMCSA has promulgated regulations under 49 CFR part 385, subpart E to address the congressional mandate on HMSPs. Those regulations are the underlying provisions to which the material incorporated by reference discussed in this rule is applicable.

V. Background

In 1986, the U.S. Department of Energy and CVSA entered into a cooperative agreement to develop a higher level of inspection procedures, out-of-service (OOS) conditions and/or criteria, an inspection decal, and a training and certification program for inspectors to conduct inspections on shipments of transuranic waste and HRCQs of RAM. CVSA developed the North American Standard Level VI Inspection Program for Transuranic Waste and Highway Route Controlled Quantities of Radioactive Material. This inspection program for select radiological shipments includes inspection procedures, enhancements to the North American Standard Level I Inspection, radiological surveys, CVSA Level VI decal requirements, and the ''North American Standard Out-of-Service Criteria and Level VI Inspection Procedures and Out-of-Service Criteria for Commercial Highway Vehicles Transporting Transuranics and Highway Route Controlled Quantities of Radioactive Materials as defined in 49 CFR part 173.403.'' As of January 1, 2005, all vehicles and carriers transporting HRCQs of RAM are regulated by the U.S. Department of Transportation. All HRCQs of RAM must pass the North American Standard Level VI Inspection prior to the shipment being allowed to travel in the United States. All highway route-controlled quantities of RAM shipments entering the United States must also pass the North American Standard Level VI Inspection either at the shipment's point of origin or when the shipment enters the United States.

Operational requirements for motor carriers transporting hazardous materials for which a HMSP is required are prescribed by § 385.415. Section 385.415(b) requires that motor carriers ensure a pre-trip inspection is performed on each motor vehicle to be used to transport a HRCQ of a Class 7 (radioactive) material, in accordance with the requirements of CVSA's handbook titled ''North American Standard Out-of-Service Criteria and Level VI Inspection Procedures and Out-of-Service Criteria for Commercial Highway Vehicles Transporting Transuranics and Highway Route Controlled Quantities of Radioactive Materials as defined in 49 CFR part 173.403.''

According to 2019 through 2022 data from FMCSA's Motor Carrier Management Information System (MCMIS), approximately 3 million Level I through Level VI inspections were performed annually. Nearly 96.3 percent

of these were Level I,[1] Level II,[2] and Level III [3] inspections. During the same period, an average of 756 Level VI inspections were performed annually, comprising only 0.03 percent of all inspections. On average, OOS violations were cited in only 6 Level VI inspections annually (0.8 percent), whereas on average, OOS violations were cited in 233,259 Level I inspections (26 percent), 264,926 Level II inspections (26 percent), and 57,990 Level III inspections (6 percent) annually. As these statistics demonstrate, OOS violations are cited in a far lower percentage of Level VI inspections than Level I, II, and III inspections, due largely to the enhanced oversight and inspection of these vehicles because of the sensitive nature of the cargo being transported.

The changes to the 2023 edition of the CVSA handbook are intended to ensure clarity in the presentation of the OOS conditions and are generally editorial or ministerial. As discussed below, FMCSA does not expect the changes made in the 2023 edition of the CVSA handbook to affect the number of OOS violations cited during Level VI inspections.

VI. Discussion of Proposed Rulemaking and Comments

A. Proposed Rulemaking

FMCSA published an NPRM on July 24, 2023 (88 FR 47437). Because the incorporation by reference found at § 385.4(b)(1) and referenced at § 385.415(b) references the outdated April 1, 2022, edition of CVSA's ''North American Standard Out-of-Service Criteria and Level VI Inspection Procedures and Out-of-Service Criteria for Commercial Highway Vehicles Transporting Transuranics and Highway Route Controlled Quantities of Radioactive Materials as defined in 49 CFR part 173.403,'' the NPRM proposed to incorporate by reference the current April 1, 2023, edition. Nine updates distinguish the April 1, 2023, edition from the 2022 edition. Each of the changes was described and discussed in detail in the NPRM. Generally, the changes serve to clarify or provide additional guidance to inspectors regarding uniform implementation and application of the OOSC, and none is expected to affect the number of OOS violations cited during Level VI inspections. The incorporation by reference of the 2023 edition does not change what constitutes a violation of FMCSA regulations.

B. Comments to the NPRM

FMCSA solicited comments concerning the NPRM for 30 days ending August 23, 2023. By that date, two comments were received: one from a private citizen supporting the NPRM, and one from CVSA, which commended FMCSA for publishing the NPRM and encouraged the Agency to finalize the rule and update the incorporation by reference.

VII. Severability

Congress authorized DOT by statute to promote safe transportation of hazardous materials in interstate commerce by prescribing, among other things, regulations and minimum standards for practices, methods, and procedures for inspections and safety permits for motor vehicles carrying certain hazardous materials (49 U.S.C. 5105(d); 49 U.S.C. 5109). The purpose of this rule is to incorporate by reference the 2023 edition of the CVSA handbook outlining the OOSC and inspection procedures for commercial highway vehicles transporting RAM. The provisions within the CVSA handbook are intended to operate holistically in addressing a range of issues necessary to ensure the safe transport of hazardous materials. However, FMCSA recognizes that certain provisions focus on unique topics. Therefore, FMCSA finds that the various provisions within the CVSA handbook are severable and able to operate functionally if one or more provisions were rendered null or otherwise eliminated. The remaining provision or provisions within the handbook will continue to operate functionally if any one or more provisions were invalidated and any other provision(s) remained. In the event a court were to invalidate one or more of the CVSA handbook's unique provisions, the remaining provisions should stand, thus allowing this congressionally mandated program to continue to operate.

VIII. Section-by-Section Analysis

Section 385.4 Matter Incorporated by Reference

Section 385.4(b)(1), as amended on December 22, 2022, references the April 1, 2022, edition of the CVSA handbook. This final rule replaces the reference to the April 1, 2022, edition date with a reference to the new edition date of April 1, 2023.

X. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), E.O. 14094 (Modernizing Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA has considered the impact of this final rule under E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, E.O. 14094 (88 FR 21879, Apr. 11, 2023), Modernizing Regulatory Review, and DOT's regulatory policies and procedures. The Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB) determined that this final rule is not a significant regulatory action under section 3(f) of E.O. 12866, as supplemented by E.O. 13563 and E.O. 14094, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. Accordingly, OMB has not reviewed it under that E.O.

The final rule updates an incorporation by reference from the April 1, 2022, edition to the April 1, 2023, edition of CVSA's handbook titled ''North American Standard Out-of-Service Criteria and Level VI Inspection Procedures and Out-of-Service Criteria for Commercial Highway Vehicles Transporting Transuranics and Highway Route Controlled Quantities of Radioactive Materials as defined in 49 CFR part 173.403.'' FMCSA reviewed its MCMIS data on inspections performed from 2019 to 2022 and does not expect the handbook updates to have any effect on the number of OOS violations cited during Level VI inspections. Therefore, the final rule's impact would de minimis.

B. Congressional Review Act

This rule is not a *major rule* as defined under the Congressional Review Act (5 U.S.C. 801–808).[4]

[1] Level I is a 37-step inspection procedure that involves examination of the motor carrier's and driver's credentials, record of duty status, the mechanical condition of the vehicle, and any hazardous materials/dangerous goods that may be present.

[2] Level II is a driver and walk-around vehicle inspection, involving the inspection of items that can be checked without physically getting under the vehicle.

[3] Level III is a driver-only inspection that includes examination of the driver's credentials and documents.

[4] A *major rule* means any rule that OMB finds has resulted in or is likely to result in (a) an annual effect on the economy of $100 million or more; (b) a major increase in costs or prices for consumers, individual industries, geographic regions, Federal, State, or local government agencies; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (5 U.S.C. 802(4)).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996,[5] requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term *small entities* comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000 (5 U.S.C. 601(6)). Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these businesses. None of the updates from the 2023 edition impose new requirements or make substantive changes to the FMCSRs.

When an Agency issues a final rule, the RFA requires the Agency to ''prepare a final regulatory flexibility analysis'' that will describe the impact of the final rule on small entities (5 U.S.C. 604(a)). Section 605 of the RFA allows an agency to certify a rule, instead of preparing an analysis, if the final rule is not expected to impact a substantial number of small entities. This rule updates an incorporation by reference found at § 385.4(b)(1) and referenced at § 385.415(b), and incorporates by reference the April 1, 2023, edition of the CVSA handbook. The changes to the 2023 edition of the CVSA handbook from the 2022 edition are intended to ensure clarity in the presentation of the OOS conditions and are generally editorial or ministerial. As noted above, FMCSA does not expect the changes made in the 2023 edition of the CVSA handbook to affect the number of OOS violations cited during Level VI inspections in the United States. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), FMCSA wants to assist small entities in understanding this rulemaking so they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the final rule affects your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman (Office of the National Ombudsman, see *https://www.sba.gov/about-sba/oversight-advocacy/office-national-ombudsman*) and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) requires Federal agencies to assess the effects of their discretionary regulatory actions.

The Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $192 million (which is the value equivalent of $100 million in 1995, adjusted for inflation to 2022 levels) or more in any 1 year. Though this rulemaking will not result in such an expenditure, and the analytical requirements of UMRA do not apply as a result, the Agency discusses the effects of this rule elsewhere in this preamble.

F. Paperwork Reduction Act

This rulemaking contains no new information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

G. E.O. 13132 (Federalism)

A rule has implications for federalism under section 1(a) of E.O. 13132 if it has ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.''

FMCSA has determined that this rulemaking does not have substantial direct costs on or for States, nor does it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

H. Privacy

The Consolidated Appropriations Act, 2005,[6] requires the Agency to assess the privacy impact of a regulation that will affect the privacy of individuals. This rulemaking does not require the collection of personally identifiable information.

I. E.O. 13175 (Indian Tribal Governments)

This rule does not have Tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

J. National Environmental Policy Act of 1969

FMCSA analyzed this rule pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321, *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680), Appendix 2, paragraph 6(b). This Categorical Exclusion (CE) covers minor revisions to regulations. The requirements in this rulemaking are covered by this CE.

List of Subjects in 49 CFR 385

Administrative practice and procedure, Highway safety, Incorporation by reference, Mexico, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, FMCSA amends 49 CFR chapter III, part 385, as set forth below:

PART 385—SAFETY FITNESS PROCEDURES

■ 1. The authority citation for part 385 continues to read as follows:

Authority: 49 U.S.C. 113, 504, 521(b), 5105(d), 5109, 5113, 13901–13905, 13908, 31135, 31136, 31144, 31148, 31151, 31502; sec. 113(a), Pub. L. 103–311, 108 Stat. 1673,

[5] Public Law 104–121, 110 Stat. 857, (Mar. 29, 1996).

[6] Public Law 108–447, 118 Stat. 2809, 3268, note following 5 U.S.C. 552a (Dec. 4, 2014).

1676; sec. 408, Pub. L. 104–88, 109 Stat. 803, 958; sec. 350, Pub. L. 107–87, 115 Stat. 833, 864; sec. 5205, Pub. L. 114–94, 129 Stat. 1312, 1537; and 49 CFR 1.87.

■ 2. Amend § 385.4 by revising paragraph (b)(1) to read as follows:

§ 385.4 Matter incorporated by reference.

* * * * *

(b) * * *

(1) ''North American Standard Out-of-Service Criteria and Level VI Inspection Procedures and Out-of-Service Criteria for Commercial Highway Vehicles Transporting Transuranics and Highway Route Controlled Quantities of Radioactive Materials as defined in 49 CFR part 173.403,'' April 1, 2023; incorporation by reference approved for § 385.415(b).

* * * * *

Issued under authority delegated in 49 CFR 1.87.

Robin Hutcheson,

Administrator.

[FR Doc. 2023–24448 Filed 11–7–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R6–ES–2022–0100; FXES11130600000–223–FF06E00000]

RIN 1018–BG79

Endangered and Threatened Wildlife and Plants; Establishment of a Nonessential Experimental Population of the Gray Wolf in Colorado

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), establish a nonessential experimental population (NEP) of the gray wolf (*Canis lupus*) in the State of Colorado, under the Endangered Species Act of 1973, as amended (Act). The State of Colorado (Colorado Parks and Wildlife or CPW) requested that the Service establish an NEP in conjunction with their State-led gray wolf reintroduction effort. Establishment of this NEP provides for allowable, legal, purposeful, and incidental taking of the gray wolf within a defined NEP area while concurrently providing for the conservation of the species. The geographic boundary of the NEP is the entire State of Colorado. The best available data indicate that reintroduction of the gray wolf into Colorado is biologically feasible and will promote the conservation of the species.

DATES: This rule is effective December 8, 2023.

ADDRESSES: This final rule, public comments on our February 17, 2023, proposed rule, a final environmental impact statement, and the record of decision, are available on the internet at *https://www.regulations.gov* at Docket No. FWS–R6–ES–2022–0100.

Information Collection Requirements: Written comments and suggestions on the information collection requirements may be submitted at any time to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803 (mail); or *Info_Coll@fws.gov* (email). Please reference ''OMB Control Number 1018–BG79'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Liisa Niva, Acting Field Supervisor, U.S. Fish and Wildlife Service, Colorado Ecological Services Field Office, 134 Union Boulevard, Suite 670, Lakewood, CO 80228; telephone 303–236–4773. 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 Service is establishing a nonessential experimental population (NEP) of the gray wolf (*Canis lupus*) in the State of Colorado, under section 10(j) of the Act.

Previous Federal Actions

Please refer to the proposed section 10(j) rule for the gray wolf in Colorado published on February 17, 2023 (88 FR 10258), for a detailed description of previous Federal actions concerning this species.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review, we solicited independent scientific review of the proposed rule. We invited seven independent peer reviewers and received four responses. The peer reviews can be found at *https://www.regulations.gov* and *https://fws.gov/library/categories/peer-review-plans.* In preparing this final rule, we incorporated the results of these reviews, as appropriate, into this final rule. A summary of the peer review comments, and our responses can be found in the *Summary of Comments and Recommendations* below.

Summary of Changes From the Proposed Rule

As a result of comments, additional data received during the comment period, and additional analysis, several changes were made to the rule we proposed on February 17, 2023 (88 FR 10258). In this final rule, we:

- Improved consistency with the State of Colorado's Wolf Restoration and Management Plan (State Plan) (CPW 2023b, entire) by clarifying that take of gray wolves attacking pets is not excepted but take of gray wolves that are attacking ''working dogs,'' or dogs that guard or herd livestock, is excepted.
- Recognized the sovereignty of Tribal nations by adding a provision to allow take of gray wolves that are significantly impacting ungulate populations on Tribal reservation lands of the Ute Mountain Ute and Southern Ute Tribes in the State of Colorado.
- Changed several terms: In regard to justification for written take authorization, ''shoot-on-sight'' is now ''depredation''; we have changed references in the proposed rule from ''problem wolves'' to ''depredating'' wolves; and ''sport hunting'' is now ''recreational harvest.''
- Clarified that a ''designated agent'' is an employee of a Federal, State, or Tribal agency who is authorized or directed by the Service to conduct management activities for the gray wolf.
- Removed the term ''relocate'' from the definition of ''remove.''
- Removed the term ''substantial income'' from the definition of ''livestock producer.''
- Clarified that take would not be excepted if there is any evidence of baiting of gray wolves, including the use of unusual attractants, artificial feeding, or intentional feeding.

Summary of Comments and Recommendations

In the proposed rule published on February 17, 2023 (88 FR 10258), we requested that all interested parties submit written comments on the proposal by April 18, 2023. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. We held public information meetings to present information and obtain feedback on March 14, 15, 16, 22, and 28, 2023. We issued news releases and posted them

on our website announcing the proposal and the dates of the public meetings. During the 60-day comment period, we received over 20,000 separate comments associated with 4,290 pieces of correspondence, including form letters with multiple signatures, such as 1 correspondence having 16,233 signatures.

Below, we summarize the substantive comments pertinent to the rulemaking and our responses to those comments. We considered substantive comments to be those that provided information relevant to our requested action, such as data, pertinent anecdotal information, or opinions backed by relevant experience or information, and literature citations. Due to the similarity of many comments, we combined multiple comments into a single, synthesized comment for many issues. We considered nonsubstantive those comments that expressed a statement or opinion without providing supporting information or relevance, restated data or information that we already have but without an alternate perspective to consider, or were beyond the scope of our proposed action. Comments from peer reviewers, Federal agencies, State agencies, and Tribes are grouped separately. All substantive information provided during the comment periods has either been incorporated directly into this final determination or is addressed below. Appendix D of our final environmental impact statement provides a full summary report of our response to comments that we received on the proposed rule.

Peer Reviewer Comments

As discussed in *Peer Review* above, we received comments on our proposed rule from four peer reviewers. We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the contents of the proposed rule. We summarize substantive peer reviewer comments below.

The peer reviewers generally concurred with our methods and conclusions and provided additional literature, information, clarifications, and suggestions to improve the final rule. For example, all four peer reviewers agreed that our description and analysis of the biology, habitat, population trends, conservation status, and distribution of the species is accurate and that our conclusions are accurate and supported by the provided evidence. Three peer reviewers shared that our proposed rule did not have any significant oversights, omissions, or inconsistencies, while one peer reviewer recommended that we more fully consider the dispersal and expansion capabilities of the species in terms of the geographic separation of the NEP. Three peer reviewers also recommended that we more fully explore the potential for individuals in the NEP to interact with the Mexican wolf (*Canis lupus baileyi*), and one peer reviewer commented that we should clarify whether the NEP would include Mexican wolves. In *Comments from States,* below, we have provided additional information regarding the Mexican wolf and clarified that this NEP applies only to the gray wolf. Finally, the peer reviewers provided additional literature for our consideration, such as an additional citation regarding the dispersal of the gray wolf into Colorado, and we incorporated the recommended literature, as needed. We address specific comments from the peer reviewers below.

Comment: A peer reviewer suggested that we may have overestimated the ability for small, newly established populations of the gray wolf to withstand high rates of human-caused mortality due to life-history traits such as high reproductive potential and dispersal capabilities.

Our response: In the past, reintroduced populations of the gray wolf in the Northern Rocky Mountains (NRM) population area demonstrated steady population growth despite low levels of human-caused mortality. However, in the final rule we have clarified that high levels of natural and human-caused mortality during the early establishment period may limit population growth and make the State of Colorado's gray wolf population goals more challenging (see *Actions and Activities in Colorado That May Affect Introduced Gray Wolves,* below).

Comment: A peer reviewer commented that the proposed rule provides take provisions for gray wolves without addressing the possibility that unusual attractants, artificial feeding, or intentional feeding may have been involved.

Our response: In the final rule, we have clarified that take would not be excepted if there is any evidence of baiting of gray wolves, including the use of unusual attractants, artificial feeding, or intentional feeding.

Comment: A peer reviewer recommended that we more thoroughly discuss or define the State of Colorado's definition of success for their reintroduction efforts.

Our response: In the final rule, we have summarized the State of Colorado's reintroduction objectives, as outlined in their management plan (CPW 2023b, entire), and clarified that our success objectives for the NEP are similar.

Federal Agency Comments

One Federal agency, the U.S. Department of Agriculture (USDA) Forest Service, provided comments on the proposed rule:

Comment: The USDA Forest Service indicated general support for the action but provided comments regarding the potential for gray wolves to disperse south out of the NEP.

Response: We provide additional information regarding this issue in *Comments From States,* below. To summarize, any wolf originating from the Colorado NEP area and dispersing beyond its borders may be managed by the wolf management regulations established for that area or may be returned to the Colorado NEP area at least until the State of Colorado achieves its recovery goals for the gray wolf.

Comments From States

We received comments from five State wildlife agencies and one State agriculture agency. The States that commented were generally supportive of the proposed rule. Three of the States expressed concern over reintroduced wolves dispersing out of the NEP and potentially interacting with the Mexican wolf and specifically requested research and scientific collection permits under section 10(a)(1)(A) of the Act to be able to return wolves to Colorado. The State of Colorado has agreed to accept the return of gray wolves to the State, until their recovery goals are achieved, at which time they will revisit this commitment (CPW 2023a). The State of Colorado's acceptance of returned gray wolves is to ensure that their restoration plan is successful. To help minimize potential interactions and to help protect Mexican wolf genetic integrity, we have simultaneously issued a section 10(a)1(A) permit to be held by the Service, which will authorize our designated agents to assist in the capture and return of wolves originating from the Colorado NEP.

Comment: Commenters stated that the Mexican wolf was listed as a separate subspecies of gray wolf in 2015, and that this listing recognized the unique physical, ecological, and genetic differences of the Mexican wolves from all other gray wolves. The commenters stated that these unique differences occurred and evolved over time due to separation of Mexican wolves from the larger gray wolves to the north, so were concerned that the proposed release and establishment of an experimental

population of larger northern wolves in Colorado closer to the wild Mexican wolf population will dramatically increase the risk of strong and irreversible genetic swamping of the Mexican wolf.

Our response: We recognize the unique characteristics of the Mexican wolf and the recovery efforts of our agency and the States of Arizona and New Mexico. We have simultaneously issued a section 10(a)(1)(A) permit to allow our designated agents to capture gray wolves that venture out of the NEP so that they may be returned to Colorado. Additionally, we do not intend to initiate or allow adaptive introgression between gray wolves and Mexican wolves as part of the genetic management of Mexican wolves (87 FR 39357, July 1, 2022).

Comment: A commenter suggested that we include information in the final rule about the State of Wyoming's predator management area, where licensing for lethal take is not needed.

Our response: This rule applies only to management activities for the gray wolf that take place within the NEP's boundary in the State of Colorado, so we have not included additional information regarding activities in the State of Wyoming.

Comment: A commenter recommended that the final rule provide assurances that the NEP wolves in Colorado will not be considered ''sensitive species'' by other Federal agencies, such as the Bureau of Land Management or the USDA Forest Service.

Our response: We do not have the authority to dictate which species receive sensitive species status under other Federal agencies' conservation frameworks.

Comment: A commenter recommended that the final rule consider all gray wolves that may disperse into the State of Utah as part of the NEP, which could allow for their immediate capture and return to the State of Colorado.

Our response: The exceptions provided in the rule are limited to the NEP area identified in the regulation (*i.e.* the State of Colorado). We use this boundary as a means to identify the NEP as required by our regulations. Any gray wolf that enters Utah will take on endangered status under the Act. Relocation of gray wolves to Colorado will be conducted under other authorities under the Act.

Comment: A commenter stated that we inconsistently define ''occupied range'' and that the State of Colorado's proposed reintroduction zones are within the species' current range.

Our response: We have verified that we use the term ''occupied range'' consistently throughout the rule. Additionally, although two male gray wolves are known to occur within the State of Colorado, they do not meet the definition of a population or a pack, as explained in this preamble to the final rule, so the NEP is wholly geographically separate from other populations of the species.

Comment: A commenter noted that the rule's requirement to report lethal or injurious take within 24 hours may be impractical due to the remoteness of some areas.

Our response: In response to this comment, we added language to the reporting requirement to give additional time when necessary.

Comment: A commenter noted that the rule should be consistent with CPW's State Plan (CPW 2023b, entire), which does not allow killing of a wolf that is attacking pets.

Our response: We have updated the final rule accordingly, so that it does not provide an exception for take of gray wolves that are attacking pets. This change improves consistency with the State of Colorado's plan. Additionally, we have added a definition for ''working dogs'' and a take exception for gray wolves that are attacking working dogs that are guarding or herding livestock. Pets are typically under the immediate control of their owner, so the owner may opportunistically harass wolves if they are encountered.

Comment: A commenter stated that annual reporting should be required for only 5 years post-reintroduction but did not provide any rationale or information to support this suggestion.

Our response: The regulatory requirements under section 10(j) of the Act for designation of a nonessential experimental population require a process for periodic review and evaluation of success or failure of the release and the effect on recovery of the species. While annual reporting is not specifically required, we must continue to periodically assess the effects of the NEP on recovery for as long as the species is federally listed. We have determined that annual reporting is appropriate, because this frequency of reporting allows for more quickly adjusting management and responding to changing conditions.

Comment: In the exception for take by landowners on their private land, the word ''their'' should be removed, because it would exclude the exception for individuals who lease private lands for livestock production but do not own the property.

Our response: We have removed the term ''their'' from the exception, such that a lessee would also be able to protect their livestock under the exception.

Comments From Tribes

We received one comment letter from a Tribe, the Southern Ute Indian Tribe. The Southern Ute Indian Tribe generally supports the action and provided comments that we summarize below along with our responses.

Comment: The Southern Ute Indian Tribe requested that the final rule include a provision to take gray wolves if they are unacceptably reducing ungulate populations. The Tribe requested that we add this provision to recognize the sovereignty of Tribal nations and to be consistent with the State of Colorado's management plan (CPW 2023b, entire) that also recognizes Tribal sovereignty.

Our response: In response to this comment, we added a provision to the rule to allow Tribes in the State of Colorado to take wolves that are having an unacceptable impact on wild ungulate herds or populations. However, the exception is limited to Tribal lands, does not include areas outside of Tribal reservation lands, and requires a science-based, peer-reviewed determination that the impacts to the ungulate populations are significant before take of gray wolves can be authorized.

Comment: The Southern Ute Indian Tribe requested that wolf management options in the rule include the removal of problem wolves (which we are now referring to as ''depredating wolves'') from Tribal land upon request.

Our response: The rule allows the Tribes to become designated agents, which will allow them to address wolf management issues. Additionally, we will be available to assist through education and training, and will continue to coordinate and assist the State and the Tribes to help resolve conflicts, as time and resources allow.

Public Comments

Comment: Commenters both supported and opposed the provisions of the rule that would allow for the lethal control of gray wolves. Some commenters asked that we prohibit most forms of lethal take of gray wolves in the NEP, with some supporting lethal take only in defense of human life. Some commenters requested that the allowable take be more liberal, while others felt that lethal control can lead to less public respect and tolerance of wolves and may encourage more poaching. Some commenters

recommended several nonlethal measures to manage depredating wolves.

Our response: The final rule recognizes that lethal take is a management tool for the gray wolf that may be necessary in specific situations, such as when nonlethal management actions are ineffective and may not resolve conflict. Nonlethal tools may be appropriate and effective in some situations, but their effectiveness depends on various characteristics of the area and individual livestock operations. For instance, many tools such as fladry (strips of fabric mounted along fencelines to deter wolves), radioactivated guard boxes, and electric fencing, are effective only in small, localized areas, and innovative tools, such as diversionary feeding, range riding, and hazing, have reduced wolf depredations in certain situations. We anticipate that lethal removal will be used as a last resort to balance conserving the species and preventing depredations.

Comment: Commenters noted that the regulations for depredation (formerly called ''shoot-on-sight'' in the proposed rule) and opportunistic and intentional harassment are too vague and that key terms like ''harassing'' and ''molesting'' are not clearly defined.

Our response: In the final rule, we have clarified the definition of ''in the act of attacking'' and provided examples of harassment activities. Our definition is consistent with section 3 of the Act and other section 10(j) rules. Additionally, the final rule now specifies the requirements to qualify for a ''depredation'' (called ''shoot-on-sight'' in the proposed rule) authorization. The terms ''take,'' ''harm,'' and ''harass'' are defined in section 3 of the Act, so we have not defined them in this rule.

Final Rule Issued Under Section 10(j) of the Act

Background

We provide detailed background information on gray wolves in the lower 48 United States in a separate Gray Wolf Biological Report (Service 2020, entire) and the 2020 final rule to delist the two currently listed *C. lupus* entities under the Act (85 FR 69778, November 3, 2020). Information in these documents is relevant to reintroduction efforts for gray wolves that may be undertaken in Colorado, and the report can be found along with this rule at *https://www.regulations.gov* in Docket No. FWS–R6–ES–2022–0100 (see *Supplemental Documents*). We summarize relevant information from these documents below.

Species Description

Gray wolves are the largest wild members of the canid (dog) family, with adults ranging in weight from 18 to 80 kilograms (40 to 175 pounds), depending on sex and geographic locale. Gray wolves are highly territorial, social animals that live and hunt in packs. They are well adapted to traveling fast and far in search of food, and to catching and eating large mammals. In North America, they are primarily predators of medium to large mammals, including deer, elk, and other species, and are efficient at shifting their diet to take advantage of available food resources (Service 2020, p. 6).

Historical and Current Range

Gray wolves have a broad circumpolar range. In the lower 48 United States, the range and number of gray wolves declined significantly during the 19th and 20th centuries primarily due to humans killing wolves through poisoning, unregulated trapping and shooting, and government-funded wolf extermination efforts (Service 2020, pp. 9–14). When we first listed two subspecies of the gray wolf under the Act in 1974, gray wolves had been eliminated from most of their historical range within the lower 48 United States. Outside of Alaska, wolves occurred in only 2 places within the lower 48 United States: An estimated 1,000 wolves persisted in northeastern Minnesota, and a small, isolated group of about 40 wolves occurred on Isle Royale, Michigan (Service 2020, pp. 12–14).

During the years since the species was reclassified in 1978, gray wolves within the lower 48 United States expanded in distribution and increased in number (Service 2020, pp. 10, 14). Gray wolves within the lower 48 United States now exist primarily in two large, stable or growing metapopulations in two separate geographic areas in the lower 48 United States—one in the western Great Lakes area of the Eastern United States and one in the Western United States (figure 1) (Service 2020, p. 27). Subpopulations of gray wolves within each of these metapopulations are well-connected as evidenced by documented movements between States and high levels of genetic diversity (Service 2020, p. 27). The western Great Lakes metapopulation consists of more than 4,200 individuals broadly distributed across the northern portions of Michigan, Minnesota, and Wisconsin (Service 2020, p. 27). This metapopulation is also connected, via documented dispersals, to the large and expansive population of about 12,000–14,000 wolves in eastern Canada. As a result, gray wolves in the Great Lakes area do not function as an isolated metapopulation of 4,200 individuals in 3 States, but rather as part of a much larger ''Great Lakes and Eastern Canada'' metapopulation (Service 2020, pp. 27–28).

BILLING CODE 4333–15–P

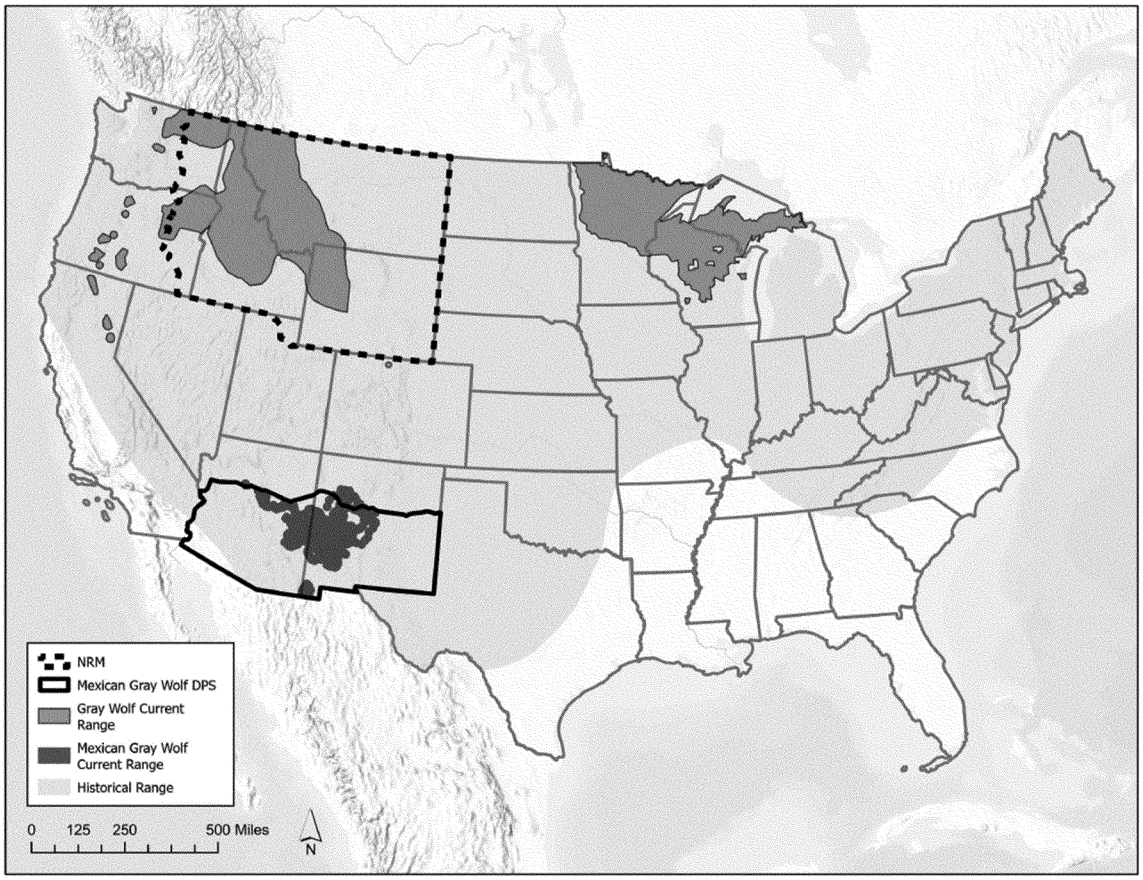


Figure 1. Historical range (Nowak 1995) and current range of gray wolves (*Canis lupus*) (as of December 2021), and Mexican wolves (as of 2022) in the lower 48 United States. NRM = The recovered Northern Rocky Mountains distinct population segment (DPS).

BILLING CODE 4333–15–C

Gray wolves in the Western United States are distributed across the NRM and into western Oregon, western Washington, northern California, and most recently in north-central Colorado (figure 1, above; Service 2020, p. 28). Based on the most current abundance estimates of gray wolves, Idaho estimated 1,337 gray wolves inhabited the State as of August 2022 (Idaho Department of Fish and Game (IDFG) 2023, unpaginated), and Montana had an estimated 1,087 gray wolves at the end of 2022 (Parks et al. 2023, pp. 9–11). In addition, the most recent year-end minimum counts for 2022 indicated at least 338 gray wolves in Wyoming, 216 wolves in Washington, 178 wolves in Oregon, and 18 in California (California Department of Fish and Wildlife (CDFW) 2022, unpaginated; Oregon Department of Fish and Wildlife (ODFW) 2023, p. 2; Washington Department of Fish and Wildlife (WDFW) et al. 2023, pp. 2–3; Wyoming Game and Fish Department (WGFD) et al. 2023, p. 3).

Until recently, only lone wolves had been confirmed in Colorado, beginning with a dispersing individual that died in 2004 from a vehicle collision (CPW 2023b, p. 4). A disperser from Wyoming was first documented in north-central Colorado during the summer of 2019 and paired up with another wolf during the winter of 2020–2021 (CPW 2023b, p. 4). This pair produced offspring in spring 2021, becoming the first documented reproductively active pack in Colorado in recent history. However, as of June 2023, only two males from this pack remain in Colorado (Eric Odell, pers. comm., CPW, June 26, 2023). The two individual wolves do not meet the definition of a population of gray wolves used by the Service for previous NEP designations in the NRM (*i.e.,* two breeding pairs successfully raising at least two pups for 2 consecutive years; Service 1994, appendix 8). In January of 2020, CPW personnel also confirmed at least six wolves traveling together in Moffatt County in northwestern Colorado (Service 2020, p. 9). Later that year, CPW personnel documented only one wolf in that area, and, at present, there is no indication that any wolf or wolves remain in that part of Colorado. As such, we do not consider any gray wolves currently found in Colorado to constitute a population.

Life Cycle

Gray wolves are highly territorial social animals and group hunters, normally living in packs of 7 or fewer but sometimes attaining pack sizes of 20 or more (Service 2020, p. 6). Wolves reach sexual maturity at 1–4 years for males and 1–5 years for females (Mech et al. 2016, entire; Wikenros et al. 2021, entire) and, once paired with a mate, may produce young annually until they are over 10 years old. Litters are born from early April into May and can range from 1 to 11 pups but generally include 5 to 6 pups (Service 2020, p. 6). Normally a pack has a single litter annually, however, multiple litters have been documented in approximately 25 percent of packs annually in Yellowstone National Park (Stahler et al.

2020, p. 52). Offspring usually remain with their parents for 10–54 months before dispersing (reviewed by Mech and Boitani 2003, p. 7; Jimenez et al. 2017, p. 1).

Habitat Use

The gray wolf is highly adaptable and can successfully occupy a wide range of habitats provided adequate prey (primarily ungulates) exists and human-caused mortality is sufficiently regulated (Mech 2017, pp. 312–315). Wolf packs typically occupy and defend a territory of 33 to more than 2,600 square kilometers (km^2) (13 to more than 1,004 square miles (mi^2)), with territories tending to be smaller at lower latitudes (Mech and Boitani 2003, p. 163; Fuller et al. 2003, pp. 187–188). The large variability in territory size is likely due to differences in pack size; prey size, distribution, and availability; lag time in population responses to changes in prey abundance; and variation in prey vulnerability (*e.g.,* seasonal age structure in ungulates) (Mech and Boitani 2003, p. 163).

To identify areas of suitable wolf habitat in the conterminous United States, researchers have used models that relate the distribution of wolves to characteristics of the landscape. These models have shown the presence of wolves is correlated with prey availability and density, livestock density, road density, human density, land ownership, habitat patch size, and forest cover (Mladenoff et al. 1995, pp. 284–292; Mladenoff et al. 1999, pp. 41–43; Carroll et al. 2003, entire; Carroll et al. 2006, p. 542; Oakleaf et al. 2006, pp. 558–559; Hanley et al. 2018, pp. 6–8).

In the Western United States, habitat models have identified suitable wolf habitat in the northern Rocky Mountains, southern Rocky Mountains (including Colorado and Utah), the Cascade Mountains of Washington and Oregon, and a small portion of the northern Sierra Nevada (Bennett 1994, entire; Switalski et al. 2002, entire; Carroll et al. 2003, entire; Carroll et al. 2006, entire; Larsen and Ripple 2006, entire; Oakleaf et al. 2006, pp. 558–559; Maletzke et al. 2015, entire; ODFW 2015, entire; Ditmer et al. 2022, entire). Large blocks of suitable habitat have been identified in the central and southern Rocky Mountains but are currently unoccupied, with the exception of occasional dispersing wolves and two male wolves in north-central Colorado.

Movement Ecology

Gray wolves rarely disperse before 10 months of age, and most commonly disperse between 1–3 years of age (Gese and Mech 1991, p. 2949; Treves et al. 2009, entire; Jimenez et al. 2017, p. 589). Generally, by the age of 3 years, most wolves will have dispersed from their natal pack to locate social openings in existing packs or find a mate and form a new pack (Service 2020, p. 7). Dispersers may become nomadic and cover large areas as lone animals, or they may locate unoccupied habitats and members of the opposite sex to establish their own territorial pack (Jimenez et al. 2017, p. 589). Dispersal distances in North America typically range from 65 to 154 kilometers (km) (40 to 96 miles) (Jimenez et al. 2017, p. 585), although dispersal distances of several hundred kilometers are occasionally reported (Jimenez et al. 2017, p. 588). The ability to disperse long distances allows populations of gray wolves to quickly expand and recolonize vacant habitats provided rates of human-caused mortality are not excessive (*e.g.,* Mech 1995, pp. 272–273; Boyd and Pletcher 1999, entire; Treves et al. 2009, entire; Jimenez et al. 2017, entire; Mech 2017, entire). However, the rate of recolonization can be affected by the extent of intervening unoccupied habitat between the source population and newly colonized area, as Allee effects (reduced probability of finding a mate at low densities) are stronger at greater distances from source populations (Hurford et al. 2006, p. 250; Stenglein and Van Deelen 2016, entire).

Causes of Decline and Threats

Targeted extirpation programs and unregulated, human-caused mortality was the primary factor that caused population declines of gray wolves across the lower 48 States during the late 1800s and early 1900s. Although there are some places wolves are not likely to persist long term due to high human or livestock densities, the regulation of human-caused mortality has been a primary factor contributing to increased wolf abundance and distribution in the lower 48 States. Regulation of human-caused mortality has significantly reduced the number of wolf mortalities caused by humans, and, although illegal and accidental killing of wolves is likely to continue with or without the protections of the Act, at current levels those mortalities have had minimal impact on the abundance or distribution of gray wolves. The high reproductive potential of wolves, and their innate behavior to disperse and locate social openings or vacant suitable habitats, allows populations of gray wolves to withstand relatively high rates of human-caused mortality (Service 2020, pp. 8–9). See *Historical and Current Range* and *Habitat Use* sections, above, for additional information.

Recovery Efforts to Date

Following our 1978 reclassification of the species under the Act, our national wolf strategy focused on conservation of gray wolves in three regions: the western Great Lakes; the NRM; and Mexican wolves in the Southwest and Mexico. We drafted recovery plans and implemented recovery programs for gray wolves in these three regions (Service 1987, entire; Service 1992, entire; Service 2017, entire). The revised NRM Wolf Recovery Plan established recovery criteria for wolves in three recovery areas across Idaho, Montana, and Wyoming (Service 1987, entire), while the Recovery Plan for the Eastern Timber Wolf (Service 1992, entire) addressed populations of gray wolves in the upper Midwest. Mexican wolves have been listed separately as an endangered subspecies of gray wolf since 2015 and are not addressed in this rule.

The currently listed entity of gray wolf, to which the Colorado NEP belongs, includes all or parts of 44 States; this listed entity encompasses populations of gray wolves in the Great Lakes States of Minnesota, Michigan, and Wisconsin as well as wolves outside the delisted NRM in the Western United States. We have not included gray wolves outside the NRM and western Great Lakes in any recovery plan. However, as noted above, the presence of gray wolves in California, western Oregon, and western Washington, as well as the two remaining wolves in Colorado, is a result of dispersal and recolonization from core populations in the NRM in addition to reproduction and dispersal from resident packs in these States and neighboring Canadian provinces.

There are no Federal recovery plans addressing wolf recovery in western States outside of Idaho, Montana, and Wyoming. However, the States of California, Colorado, Oregon, Washington, and Utah have demonstrated a commitment to wolf conservation by developing management plans or codifying laws and regulations that provide mechanisms to regulate wolf mortality, similar to most other species of wildlife managed under State authority. This includes the passage of a voter-led initiative in Colorado calling specifically for the reintroduction of gray wolves to the western portion of the State (Colorado Revised Statute 33–2–105.8). At the end of 2022, 10 packs of gray wolves (totaling at least 52 wolves and 6 breeding pairs) were

documented in western Washington where wolves are federally listed (WDFW et al. 2023, p. 17). In the western two-thirds of Oregon, where gray wolves are federally listed, there were a minimum of 38 wolves in 10 groups (ODFW defines a group as 2 or more wolves traveling together (ODFW 2023, p. 4)); 4 of these groups were considered breeding pairs at the end of 2022 (ODFW 2023, pp. 5–6). Wolves originating from Oregon have also expanded their range into California, where a minimum of 18 wolves in 3 packs were documented at the end of 2022 (CDFW 2022, entire).

In addition to gray wolves found in the western States outside of the delisted NRM population, the Great Lakes metapopulation, consisting of more than 4,200 wolves, is broadly distributed across Minnesota, Michigan, and Wisconsin (Erb and Humpal 2022, entire; Wisconsin Department of Natural Resources (WI DNR) 2022, entire; Michigan Department of Natural Resources (MI DNR) 2023, entire). Recently, both Michigan and Minnesota updated their State wolf management plans (MI DNR 2022, entire; Minnesota Department of Natural Resources 2023, entire). The WI DNR recently revised their draft wolf management plan and will present it to their Natural Resource Board in October 2023 to determine next steps to finalize the plan (WI DNR 2023, entire).

The NRM Wolf Recovery Plan was approved in 1980 (Service 1980, p. i) and revised in 1987 (Service 1987, p. i). The recovery goal for the NRM was reevaluated and, when necessary, modified as new scientific information warranted (Service 1987, p. 12; Service 1994, appendices 8 and 9; Fritts and Carbyn 1995, p. 26; Bangs 2002, p. 1; 73 FR 10514, February 27, 2008; 74 FR 15123, April 2, 2009). The Service's resulting recovery goal for the NRM population of gray wolves was 30 or more breeding pairs, defined as an adult male and an adult female wolf that have produced at least 2 pups that survived until December 31 of the year of their birth during the previous breeding season (Service 1994), comprising at least 300 wolves equitably distributed among Idaho, Montana, and Wyoming for 3 consecutive years, with genetic exchange (either natural or, if necessary, agency managed) between subpopulations. To provide a buffer above these minimum recovery levels, each State was to manage for at least 15 breeding pairs and 150 wolves in midwinter (77 FR 55530 at 55538–55539, September 10, 2012; 74 FR 15123 at 15132, April 2, 2009). For additional information on NRM wolf recovery goals, see 74 FR 15123 (April 2, 2009) at pp. 15130–15135 and references therein.

Wolves in the NRM distinct population segment (DPS) have recovered and were delisted. The NRM population achieved its numerical and distributional recovery goals at the end of 2000 (Service et al. 2008, table 4). The temporal portion of the recovery goal was achieved in 2002 when the numerical and distributional recovery goals were exceeded for the third successive year (Service et al. 2008, table 4). In 2009, we concluded that gray wolves in the NRM far exceeded recovery goals. We also concluded that the NRM population: (1) Had at least 45 reproductively successful packs and 450 individual wolves each winter (near the low point in the annual cycle of a wolf population); (2) was equitably distributed within the 250,000-km^2 (100,000-mi^2) area containing 3 areas of large core refugia (National Parks, wilderness areas, large blocks of remote secure public land) and at least 170,228 km^2 (65,725 mi^2) of suitable wolf habitat; and (3) was genetically diverse and had demonstrated successful genetic exchange through natural dispersal and human-assisted migration management between all 3 core refugia (74 FR 15123, April 2, 2009). Gray wolves in the NRM remain well above the recovery goals established for this region (see *Historical and Current Range,* above).

Reintroduction

To date, purposeful reintroduction of gray wolves to Colorado has not occurred; current wolf occupancy in Colorado is the result of natural wolf dispersal from the NRM population (Service 2020, pp. 15–19, 28; see *Historical and Current Range,* above). The reintroduction of gray wolves in Idaho and Wyoming in the 1990s contributed to achieving the recovery goals for the NRM population in 2002 (Service et al. 2008). For additional details on NRM reintroduction efforts, please see our biological report (Service 2020, entire) and *Release Procedures* in this document, below.

Regulatory Framework

Section 9 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the prohibitions afforded to threatened and endangered species. Section 9 of the Act prohibits take of endangered wildlife. ''Take'' is defined by the Act as harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct. Section 7 of the Act outlines the procedures for Federal interagency cooperation to conserve federally listed species and protect designated critical habitat. It mandates that all Federal agencies use their existing authorities to further the purposes of the Act by carrying out programs for the conservation of listed species. It also requires that Federal agencies, in consultation with the Service, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Section 7 of the Act does not affect activities undertaken on private land unless they are authorized, funded, or carried out by a Federal agency.

The 1982 amendments to the Act (16 U.S.C. 1531 *et seq.*) included the addition of section 10(j), which allows for populations of listed species planned to be reintroduced to be designated as ''experimental populations.'' The provisions of section 10(j) were enacted to ameliorate concerns that reintroduced populations will negatively impact landowners and other private parties, by giving the Secretary of the Interior greater regulatory flexibility and discretion in managing the reintroduced species to encourage recovery in collaboration with partners, especially private landowners. Under section 10(j) of the Act, and our implementing regulations at 50 CFR 17.81, the Service may designate as an experimental population a population of an endangered or threatened species that will be released into habitat that is capable of supporting the experimental population outside the species' current range. Under section 10(j) of the Act, we determine whether or not an experimental population is essential to the continued existence of the species based on the best available science. Our regulations define an essential population as one whose loss would be likely to appreciably reduce the likelihood of the survival of the species in the wild. All other experimental populations are to be classified as ''nonessential'' (50 CFR 17.80(b)).

We treat any population determined by the Secretary to be an experimental population as if we had listed it as a threatened species for the purposes of establishing protective regulations with respect to that population (50 CFR 17.82). The designation as an experimental population and treatment as a threatened species allows us to develop tailored ''take'' prohibitions that are necessary and advisable to provide for the conservation of the species. The protective regulations

adopted for an experimental population will contain applicable prohibitions, as appropriate, and exceptions for that population, allowing us discretion in devising management programs to provide for the conservation of the species.

Section 7(a)(2) of the Act requires that Federal agencies, in consultation with the Service, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or adversely modify its critical habitat. For the purposes of section 7 of the Act, we treat an NEP as a threatened species when the population is located within a National Wildlife Refuge or unit of the National Park Service (50 CFR 17.83; see 16 U.S.C. 1539(j)(2)(C)(i)). When NEPs are located outside of a National Wildlife Refuge or National Park Service unit, for the purposes of section 7, we treat the population as proposed for listing and only sections 7(a)(1) (50 CFR 17.83) and 7(a)(4) (50 CFR 402.10) of the Act apply (50 CFR 17.83). In these instances, NEPs provide additional flexibility in managing the nonessential population because Federal agencies are not required to consult with us under section 7(a)(2). Section 7(a)(1) requires all Federal agencies to use their authorities to carry out programs for the conservation of listed species. Section 7(a)(4) requires Federal agencies to confer (rather than consult) with the Service on actions that are likely to jeopardize the continued existence of a species proposed to be listed. As a result, NEPs provide additional flexibility in managing the nonessential population.

Section 10(j)(2)(C)(ii) of the Act states that critical habitat shall not be designated for any experimental population that is determined to be nonessential. Accordingly, we cannot designate critical habitat in areas where we establish an NEP.

Before authorizing the release as an experimental population of any population (including eggs, propagules, or individuals) of an endangered or threatened species, and before authorizing any necessary transportation to conduct the release, the Service must find by regulation that such release will further the conservation of the species. In making such a finding the Service uses the best scientific and commercial data available to consider:

(1) Any possible adverse effects on extant populations of a species as a result of removal of individuals, eggs, or propagules for introduction elsewhere (see *Effects on Wild Populations,* below);

(2) The likelihood that any such experimental population will become established and survive in the foreseeable future (see *Likelihood of Population Establishment and Survival,* below);

(3) The relative effects that establishment of an experimental population will have on the recovery of the species (see *Effects of the NEP on Recovery Efforts,* below);

(4) The extent to which the introduced population may be affected by existing or anticipated Federal or State actions or private activities within or adjacent to the experimental population area (see *Likelihood of Population Establishment and Survival,* below); and

(5) When an experimental population is being established outside of its historical range, any possible adverse effects to the ecosystem that may result from the experimental population being established.

Furthermore, as set forth at 50 CFR 17.81(c), all regulations designating experimental populations under section 10(j) of the Act must provide:

(1) Appropriate means to identify the experimental population, including, but not limited to, its actual or proposed location, actual or anticipated migration, number of specimens released or to be released, and other criteria appropriate to identify the experimental population (see *Experimental Population* and *Experimental Population Regulation Requirements,* below);

(2) A finding, based solely on the best scientific and commercial data available, and the supporting factual basis, on whether the experimental population is, or is not, essential to the continued existence of the species in the wild (see *Is the Experimental Population Essential or Nonessential?,* below);

(3) Management restrictions, protective measures, or other special management concerns for that population, which may include, but are not limited to, measures to isolate, remove, and/or contain the experimental population designated in the regulations from nonexperimental populations (see *Management Restrictions, Protective Measures, and Other Special Management,* below); and

(4) A process for periodic review and evaluation of the success or failure of the release and the effect of the release on the conservation and recovery of the species (see *Review and Evaluation of the Success or Failure of the NEP,* below).

Under 50 CFR 17.81(e), the Service must consult with appropriate State fish and wildlife agencies, affected Tribal governments, local governmental entities, affected Federal agencies, and affected private landowners in developing and implementing experimental population rules. To the maximum extent practicable, section 10(j) rules represent an agreement between the Service, the affected State and Federal agencies, Tribal governments, local governments, and persons holding any interest in land or water that may be affected by the establishment of an experimental population.

Experimental Population

We are designating this NEP at the request of CPW, to facilitate their planned reintroduction of gray wolves to the State per the requirements of Proposition 114 (now codified as Colorado Revised Statute 33–2–105.8), which directs the CPW Commission to take the steps necessary to reintroduce gray wolves to lands west of the Continental Divide by December 31, 2023.

Reintroduction Areas and Release Sites

The NEP area is the entire State of Colorado. This scale is appropriate, given that CPW has proposed a discrete release area (figure 2), and gray wolves have high dispersal ability (Jimenez et al. 2017, p. 582). Furthermore, gray wolves released on the west side of the Continental Divide may move to locations beyond the western portion of the State, including east of the Continental Divide. Within the statewide NEP designation, CPW proposes to release gray wolves obtained from the delisted NRM population (Idaho, Montana, eastern Oregon, eastern Washington, Wyoming) at multiple sites west of the Continental Divide. Individual release sites will be located on private or State lands with high habitat suitability and low wolf–livestock conflict risk based on models developed by Ditmer et al. (2022, entire). All release sites will be located west of the Continental Divide (Colorado Revised Statute 33–2–105.8) (figure 2). CPW proposes to release a total of 10 to 15 wolves at a 50:50 sex ratio each year during winter for 3 to 5 years (CPW 2023b, p. 20), although exact numbers and sex ratios may vary due to factors associated with capture from source populations (CPW 2023b, Appendix B, p. B–34). After initial releases are completed, CPW will monitor the success of reintroduction efforts and document wolf abundance and distribution annually to evaluate progress toward meeting State wolf recovery objectives (CPW 2023b, p. 22).

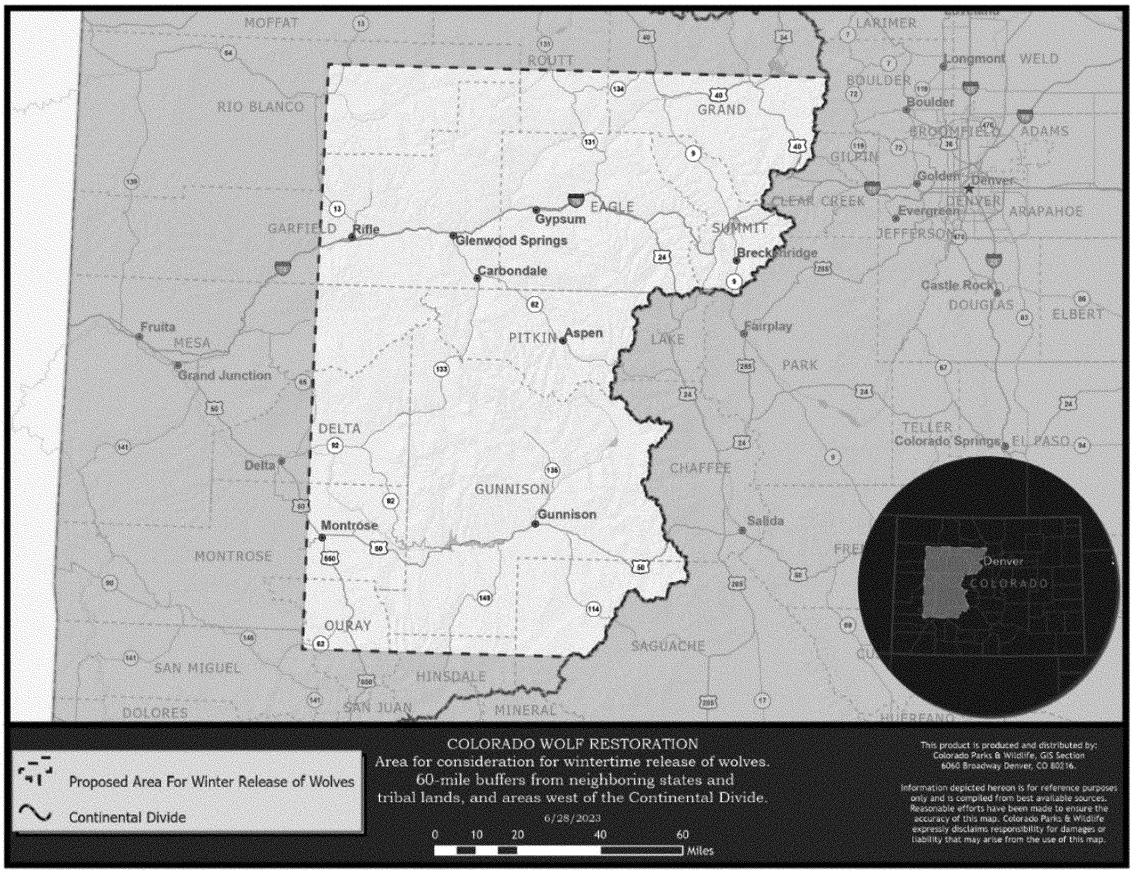


Figure 2. Map of the State of Colorado with county boundaries and the general area for CPW's proposed initial (1–3 years) release site area for a nonessential experimental population (NEP) of gray wolves. Used with permission from CPW.

Release Procedures

CPW officials plan to capture wild gray wolves in cooperating States in the Western United States where wolves are federally delisted (Montana, Idaho, Wyoming, the eastern third of Washington and Oregon, and north-central Utah) using a combination of net gunning, helicopter darting, or trapping. Wolf captures will be conducted in accordance with approved protocols specific to each jurisdiction from which donor wolves are to come. Animals will be a mix of sex and age classes, with a sex ratio of 50:50 preferred, and ideally donor animals will be unrelated and of dispersing age (2 years and older). Each wolf selected for transport will be photographed, examined to evaluate condition and to obtain biological measurements and samples, tested for diseases, vaccinated for a wide variety of diseases, and treated for internal and external parasites. Additionally, wolves will be fitted with either a global positioning system (GPS) or a very high frequency (VHF) radio transmitter as well as other markers to assist with individual identification. Captured animals will be transported to Colorado in large, aluminum crates (similar to those used for wolf reintroduction in the NRM) by aircraft, ground transportation, or a mix of techniques, with a goal of releasing captured animals as quickly as possible to minimize time in captivity and capture-related stress. All animals will be ''hard released'' (released shortly after transport to reintroduction sites with no preconditioning; CPW 2021b, pp. 19–21) during winter (November through March), with no acclimation time between capture, transport, and release. The Final Report on Wolf Restoration Logistics Recommendations developed by the Colorado Wolf Restoration and Management Plan Technical Working Group (CPW 2021b, entire) provides additional details regarding the proposed release procedures.

Reintroduction Site Management

As noted in *Reintroduction Areas and Release Sites* and *Release Procedures* above, the CPW plans to ''hard release'' gray wolves on State or private lands within a discrete release area (figure 2, above). Given that gray wolves released in this manner are more likely to disperse immediately from the release site rather than remain together at the site (CPW 2021b, entire), CPW does not plan to implement any special management practices at individual release sites. For additional information, please see the State of Colorado's Final Report on Wolf Restoration Logistics Recommendations (CPW 2021b, entire).

How will the NEP further the conservation of the species?

Under 50 CFR 17.81(b), before authorizing the release as an experimental population, the Service must find by regulation that such release will further the conservation of the species. We explain our rationale for making our finding below. In making such a finding, we must consider effects on donor populations, the likelihood of establishment and survival of the experimental population, the effects that establishment of the experimental population will have on recovery of the species, and the extent to which the

experimental population will be affected by Federal, State, or private activities.

Effects on Wild Populations

Our regulations at 50 CFR 17.81 require that we consider any possible adverse effects on extant populations of a species as a result of removal of individuals, eggs, or propagules for introduction elsewhere. The preferred donor population for the reintroduction of gray wolves to Colorado is the delisted NRM population. Gray wolves in these States are managed by State fish and wildlife agencies and Tribes. These wolves are an appropriate source for the Colorado reintroduction because they share similarities in habitat and preferred prey; one of the wolves in Colorado dispersed from the NRM population; and the NRM population reached numerical, spatial, and temporal recovery goals by the end of 2002 (Service 2020, p. 15; see *Recovery Efforts to Date,* above). The NRM wolf population continues to demonstrate stable to slightly increasing demographic trends with an estimated 1,337 wolves in Idaho as of August 2022 and slightly more than 1,800 wolves in Montana, Oregon, Washington, and Wyoming at the end of 2022 (IDFG 2023, unpaginated; ODFW 2023, p. 2; Parks et al. 2023, pp. 9–11; WDFW et al. 2023, pp. 2–3; WGFD et al 2023, p. 3). Further, the NRM population is part of a larger metapopulation of wolves that encompasses all of Western Canada (Service 2020, p. 29). Given the demonstrated resilience and recovery trajectory of the NRM population and limited number of animals that will be captured for translocation, we expect negative impacts to the donor population to be negligible.

Likelihood of Population Establishment and Survival

In our findings for designation of an NEP, we must consider if the reintroduced population will become established and survive in the foreseeable future. In this portion of the preamble, we address the likelihood that populations introduced into the NEP will become established and survive. In defining the experimental population boundary, we attempted to encompass the area where the population is likely to become established in the foreseeable future. The term ''foreseeable future'' appears in the Act in the statutory definition of ''threatened species.'' However, the Act does not define the term ''foreseeable future.'' Similarly, our implementing regulations governing the establishment of an NEP under section 10(j) of the Act use the term ''foreseeable future'' (50 CFR 17.81(b)(2)) but do not define the term. However, our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis.

The term foreseeable future extends only so far into the future as we can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. While we use the term ''foreseeable future'' here in a different context (to determine the likelihood of population establishment and to establish boundaries for identification of the experimental population), we apply a similar conceptual framework. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant effects of release and management of the species and to the species' likely responses in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

For the purposes of this rule, we define the foreseeable future for our evaluation of the likelihood of survival and establishment as approximately 13 years, which reflects 3 wolf generations of approximately 4–4.5 years per generation (vonHoldt et al. 2008, p. 257; Mech et al. 2016, pp. 1,6), and the time horizon within which we can reasonably forecast population expansion of gray wolves in Colorado given the results of previous reintroduction efforts of gray wolves in the NRM. This timeframe is also similar to the amount of time it took wolves to begin recolonizing areas outside of the core of the NRM (Idaho, Montana, and Wyoming) in Oregon and Washington (Service 2020, p. 28).

In evaluating the likelihood of establishment and survival of this NEP in the foreseeable future, we considered the extent to which causes of extirpation in the NEP area have been addressed, habitat suitability and prey availability within the NEP area, and existing scientific and technical expertise and experience with reintroduction efforts. As discussed below, we expect that gray wolves will become established during this time span, given the species' adaptability and dispersal ability.

Addressing Causes of Extirpation Within the Experimental Population Area

Investigating the causes for the extirpation of gray wolves is necessary to understand whether we are sufficiently addressing threats to the species in the NEP so that reintroduction efforts are likely to be successful. The International Union for the Conservation of Nature's Guidelines for Reintroduction and Other Conservation Translocations (IUCN 2013, p. 4) identifies several criteria to consider prior to undertaking a reintroduction, including ''strong evidence that the threat(s) that caused any previous extinction have been correctly identified and removed or sufficiently reduced.'' Wolves depend on abundant prey (primarily ungulates) and can successfully colonize and occupy a wide range of habitats as long as human-caused mortality is adequately managed (Mech 2017, pp. 312–315). Historical wolf declines in Colorado resulted from purposeful efforts to eradicate the species by State and Federal authorities, primarily due to conflicts with domestic livestock production (Service 2020, pp. 9–14; see *Habitat Use* and *Causes of Decline and Threats,* above, for additional information). In 2004, CPW created a Wolf Management Working Group, largely in response to dispersal of wolves from the NRM population to Colorado and other western States. The working group developed a series of recommendations for wolf management in Colorado, including recognition of the ecological value of wolves and an intent to accept their presence in Colorado (Colorado Wolf Management Working Group 2004, p. 3). The recommendations of the Wolf Management Working Group were formally adopted by the Colorado Wildlife Commission in 2005 and were reaffirmed by the CPW Commission in 2016 (85 FR 69778 at 69837, November 3, 2020).

The State of Colorado currently classifies the gray wolf as an endangered species; this classification regulates take. The State of Colorado expanded its conservation efforts for gray wolves through the passage of Proposition 114 (now codified as Colorado Revised Statute 33–2–105.8), which directs the CPW Commission to take the steps necessary to reintroduce gray wolves to lands west of the Continental Divide by December 31, 2023. Colorado Revised Statute 33–2–105.8 calls for the development and implementation of a Colorado Wolf Restoration and Management Plan, which was finalized

and approved by the CPW Commission in May 2023 (CPW 2023b, entire). The plan follows a phased approach whereby the conservation status of gray wolves is linked with numerical and temporal population targets (CPW 2023b, pp. 24–25). Although agency-directed lethal control may be used to mitigate conflicts with specific individual wolves and/or packs that repeatedly depredate livestock, purposeful eradication of wolves in Colorado is no longer a tool used for wolf management. Lethal control may consist of removing wolves that repeatedly depredate on livestock, whereas purposeful eradication likely involves removal of all wolves within the State. Based on the elimination of purposeful eradication, and the fact that gray wolves are protected under State and Federal laws, we do not anticipate the original cause of wolf extirpation from Colorado to be repeated.

Habitat Suitability/Prey Availability

Excluding occasional dispersing wolves and two known individual wolves presently in north-central Colorado, large blocks of gray wolf habitat in the central and southern Rocky Mountains are not currently occupied by gray wolves. Models developed to assess habitat suitability and the probability of wolf occupancy indicate that Colorado contains adequate habitat to support a population of gray wolves, although the number of wolves that the State could support varies among the models. One model estimated that the State could support between 407 and 814 wolves based on prey and habitat availability (Bennett 1994, pp. 112, 275–280).

Carroll et al. (2003, entire) examined multiple models to evaluate suitable wolf habitat, occupancy, and the probability of wolf persistence given various landscape changes and potential increases in human density in the southern Rocky Mountains, which includes portions of southeastern Wyoming, Colorado, and northern New Mexico. Using a resource selection function (RSF) model developed for wolves in the Greater Yellowstone Ecosystem and projecting it to Colorado, Carroll et al. (2003, pp. 541–542) identified potential wolf habitat across north-central and northwest Colorado and the southwestern part of the State. RSF model predictions indicate that Colorado could support an estimated 1,305 wolves with nearly 87 percent of wolves occupying public lands in the State. Carroll et al. (2003, entire) also used a dynamic model that incorporated population viability analysis to evaluate occupancy of gray wolves and persistence based on current conditions as well as potential changes resulting from increased road and human densities in the future. The dynamic model based on current conditions predicted similar distribution and wolf population estimates as the RSF model; however, as predicted, as road and human densities increased in Colorado, the availability of suitable habitat and the estimated number of wolves that habitat could support declined (Carroll et al. 2003, pp. 541–543).

An analysis similar to that of Carroll et al. (2003, entire) was conducted for the entirety of the Western United States and indicated that high-quality wolf habitat exists in Colorado and Utah, but that wolves recolonizing Colorado and Oregon would be most vulnerable to landscape changes because these areas lack, and are greater distances from, large core refugia (Carroll et al. 2006, pp. 33–36). The authors proposed that habitat improvements, primarily in the form of road removal or closures, could mitigate these effects (Carroll et al. 2006, p. 36). Switalski et al. (2002, pp. 12–13) and Carroll et al. (2003, p. 545) also cautioned that model predictions may be inaccurate because they did not account for the presence of livestock and the potential use of lethal removal to mitigate conflicts, which could affect the long-term persistence of wolves in some areas (Mech et al. 2019, entire).

Recognizing the limitations of wolf habitat suitability models that do not account for the presence of livestock, Ditmer et al. (2022, entire) used voting records for proposition 114 in Colorado to quantify and map an index of tolerance for wolves and combined it with spatially explicit data on livestock distributions and land ownership to predict wolf conflict risk in Colorado (Ditmer et al. 2022, p. 1). Conflict risk was juxtaposed with estimates of wolf ecological suitability developed using seasonal prey densities along with environmental and anthropogenic features that influence wolf habitat use (Ditmer et al. 2022, p. 1) to predict areas of high habitat suitability and increased conflict risk in summer and winter for gray wolves across Colorado. The models predicted over 58 million acres (23 million hectares) of potential suitable gray wolf habitat occurs on the western slope of Colorado. Approximately 56 percent of this total, or 32.5 million acres (13.2 million hectares) was considered suitable seasonal wolf habitat that contained high ecological suitability and low conflict risk (Ditmer et al. 2022, p. 11). However, approximately 14 percent, or 8.3 million acres (3.4 million hectares), the majority of which occurs in the northern part of the western slope of Colorado, were identified as being potential conflict hotspots where significant overlap between ecological suitability and conflict risk was predicted (Ditmer et al. 2022, pp. 9–11).

Wolves can successfully occupy a wide range of habitats provided adequate prey exists (Mech 2017, pp. 312–315). Wolves in the Western United States rely on habitats containing large prey such as mule deer, elk, and moose (Smith et al. 2010, entire). CPW manages wild ungulate populations, such as moose, elk, bighorn sheep, and mule deer, etc., using herd management plans, which establish population objective minimums and maximums for each ungulate herd in the State (CPW 2020, entire). The herd management plans consider both biological and social factors when setting herd objective ranges (CPW 2020, entire). Like other Western States, mule deer in Colorado have declined due to a multitude of factors since the 1970s to a statewide post-hunt population estimate of 416,430 animals in 2021, which was well below the target statewide population objective of 484,100. In 2021, of 54 mule deer herds in Colorado, 18 were below their population objective minimum with the western part of the State being the most affected. In contrast, elk populations in Colorado are stable with a 2021 post-hunt population estimate of 308,920 elk. Although 34 of 42 elk herds are within or above the population objective range, the ratio of calves per 100 cows (a measure of overall herd fitness) has been on the decline in some southwestern herd units (CPW 2020, p. 7).

Moose are not native to Colorado so, to create hunting and wildlife viewing opportunities, CPW transplanted moose to the State beginning in 1978. Since then, they transplanted moose on four other occasions through 2010. The 2021 post-hunt moose population was estimated at 3,510 animals and continues to increase as moose expand into new areas of Colorado. In summary, while deer and elk numbers are down from their peak populations in some parts of Colorado, they still number in the hundreds of thousands of individuals, and the State is actively managing populations to meet objectives (CPW 2020, entire). Introduced moose provide an additional potential food resource for wolves in some parts of the State. Therefore, wolf habitat and prey are suitable and abundant within the NEP area and would support population establishment and survival.

Reintroduction Expertise/Experience/Track Record

Conservation efforts to reintroduce gray wolves to the NRM began in 1995, with the reintroduction of wolves to portions of Idaho and Wyoming and the continued natural recolonization of wolves in northwestern Montana. Following their release, wolves rapidly increased in abundance and distribution in the region due to natural reproduction and the availability of high-quality, suitable wolf habitat in the NRM. Between 1995 and 2008, populations of gray wolves in the NRM increased an average of 24 percent annually, reaching 1,655 wolves by the end of 2008 (Service et al. 2016, table 6b), while total mortality averaged approximately 16 percent annually between 1999 and 2008 (Service et al. 2000–2009, entire). Wolf numbers and distribution in Idaho, Montana, and Wyoming stabilized after 2008 as suitable habitat became increasingly saturated (74 FR 15123 at 15160, April 2, 2009).

Between 2009 and 2015, when gray wolves were managed primarily under State authority due to delisting (73 FR 10514, February 27, 2008; 74 FR 15123, April 2, 2009; 76 FR 25590, May 5, 2011; 77 FR 55530, September 10, 2012), Idaho, Montana, and Wyoming began to manage wolves with the objective of reversing or stabilizing population growth while continuing to maintain populations well above Federal recovery targets for the NRM population. During this period, States began to use public harvest as a management tool to achieve State-specific management objectives. As a result, during those years when legal harvest occurred, total wolf mortality in the NRM increased to an average of 29 percent of the minimum known population (Service et al. 2010–2016, entire), while population growth declined to an average of approximately 1 percent annually (Service et al. 2010–2016, entire). Although this mortality rate was significantly higher than mortality rates during the previous decade, the NRM population demonstrated an ability to sustain itself, consistent with scientific information demonstrating that the species' reproductive and dispersal capacity can compensate for a range of mortality rates (Service 2020, pp. 8–9).

As of 2015, the final year of a combined NRM wolf count at the end of federally required post-delisting monitoring in Idaho and Montana, wolves in the NRM remained well above minimum recovery levels with a minimum known population of 1,704 wolves distributed across Idaho, Montana, and Wyoming. An additional 177 wolves were documented in the NRM portions of Oregon and Washington at the end of 2015. Wolves in the NRM continue to remain above minimum recovery levels, demonstrating availability of technical expertise to successfully reintroduce gray wolf populations. For more information regarding the success of reintroduction efforts in the NRM, please see *Recovery Efforts to Date,* above.

Based on the success of past gray wolf reintroduction efforts in the NRM where biological recovery was achieved within 7 years, the availability of suitable wolf habitat and adequate wild ungulate prey in the NEP (see *Habitat suitability/prey availability,* above), the demonstrated resiliency of gray wolves in the United States, and the development of a comprehensive Gray Wolf Restoration and Management Plan in Colorado, the best available scientific data indicate that the reintroduction of gray wolves into suitable habitat in Colorado supports the likely success of establishment and survival of the reintroduced population, and the experimental population has a high likelihood of becoming established within the foreseeable future.

Effects of the NEP on Recovery Efforts

We are designating an experimental population of gray wolf in Colorado to support CPW's planned effort to reintroduce gray wolves to the State of Colorado and to further the conservation of the currently listed 44-State entity. CPW developed a Gray Wolf Restoration and Management Plan for the reintroduction and management of gray wolves in the State, with the goal of restoring the species to Colorado in a phased approach to the point where it no longer needs protection under State statute (CPW 2023b, entire). This management plan focuses on the primary threat to gray wolf populations, which is human-caused mortality (*e.g.,* Fuller et al. 2003, entire; Mech 2017, pp. 311–312; Hill et al. 2022, entire).

As noted in *Recovery Efforts to Date,* above, populations of gray wolves in the 44-State listed entity number more than 4,300 individuals and occupy portions of California, Michigan, Minnesota, Oregon, Washington, and Wisconsin (CDFW 2022, unpaginated; Erb and Humpal 2022, unpaginated; WI DNR 2022, p. 4; ODFW 2023, p. 2; WDFW et al. 2023, pp. 2–3). Two gray wolves are currently known to be present in Colorado, and they do not currently meet our definition of a gray wolf population, which is two breeding pairs of gray wolves that each successfully raise at least two young to December 31 of their birth year for 2 consecutive years (Service 1994). As explained above in *Recovery Efforts to Date,* there is no recovery plan that addresses the entire currently listed entity. In the absence of a recovery plan, we evaluate how the experimental population will contribute to the conservation of the species by considering the conservation biology principles of redundancy, resiliency, and representation.

Reintroduction efforts in Colorado will provide additional redundancy and representation for the 44-State listed entity. Redundancy is the ability for the species to withstand catastrophic events, for which adaptation is unlikely, and is associated with the number and distribution of populations. Representation is the ability of a species to adapt to changes in the environment and is associated with its ecological, genetic, behavioral, and morphological diversity. Once established, the reintroduction in the NEP will improve redundancy by increasing the number of populations at the southern extent of the currently occupied range and representation by increasing the ecological diversity of the habitats occupied by the listed entity. For these reasons, reintroduction efforts undertaken by CPW will increase the redundancy and representation, and hence viability, of the currently listed 44-State entity (*e.g.,* Smith et al. 2018).

Previous NEP designations have conserved and recovered gray wolves in other regions of the United States, particularly in the NRM. Additional management flexibility, relative to the mandatory prohibitions covering nonessential experimental species under the Act, is expected to help address local, State, and Tribal concerns about wolf-related conflicts in Colorado, similar to those experienced in other NRM States. Addressing these concerns proactively may result in greater human acceptance of gray wolves and other species of concern. Based on past modeling efforts, it has been estimated that Colorado could biologically support approximately 400 to 1,200 wolves (Bennett 1994, pp. 112, 275–280; Carroll et al. 2006, p. 33), but due to social constraints that could limit the distribution of wolves in the State (Ditmer et al. 2022, p. 12), the total number of wolves that Colorado could support may be slightly lower. Nonetheless, this action will contribute to the conservation of the listed entity by increasing redundancy and representation.

Actions and Activities in Colorado That May Affect Introduced Gray Wolves

A large proportion of Colorado is composed of publicly owned Federal lands (approximately 36 percent; Congressional Research Service 2020). Public lands include National Forests, National Parks, National Monuments, and National Wildlife Refuges, which comprise approximately 63 percent of all public lands in Colorado. In addition, the Bureau of Land Management manages approximately 35 percent of public land in Colorado, much of which is located in the western portion of the State where reintroduction efforts for gray wolves will take place (figure 2, above). Although much of this public land is largely unavailable and/or unsuitable for intensive development and contains an abundance of wild ungulates, livestock grazing does occur on public lands in Colorado, which may increase the potential for mortality of gray wolves from lethal control of chronically depredating packs. However, in both Minnesota and the northern Rocky Mountains, lethal control of depredating wolves has had little effect on wolf distribution and abundance (Service 2020, p. 22; 85 FR 69778 at 69842, November 3, 2020).

Humans sparsely inhabit most of the NEP area containing suitable habitat for gray wolves. However, the NEP area contains human infrastructure and activities that pose some risk to success of the NEP. Risks include wolves killed as a result of mistaken identity, accidental capture during animal damage control activities, and high-speed vehicular traffic. Human-caused mortality includes both controllable and uncontrollable sources of mortality. Controllable sources of mortality are discretionary, can be limited by the managing agency, and include permitted take, recreational harvest, and direct agency control. Sources of mortality that will be difficult to limit, or may be uncontrollable, occur regardless of population size and include things such as natural mortalities, illegal take, and accidental deaths (*e.g.,* vehicle collisions, capture-related mortalities) (85 FR 69778, November 3, 2020). Although the effects of uncontrollable sources of mortality may be greatest for wolf populations that are small in size, which is most likely to occur during the early phases of recovery in Colorado, based on experiences with wolf recovery in the NRM (where uncontrollable sources of mortality were also present) and the availability of suitable habitat in Colorado, we expect that these sources of mortality will have minimal effect on gray wolf population growth and persistence in the State. If population levels and controllable sources of mortality are adequately regulated, the life-history characteristics of wolf populations provide natural resiliency to relatively high levels of human-caused mortality (85 FR 69778, November 3, 2020).

In conjunction with previous reintroduction efforts, implementation of this final rule reflects continuing success in recovering gray wolves through longstanding cooperative and complementary programs by several Federal, State, and Tribal agencies. In particular, the stakeholder engagement process developed by CPW in support of its Gray Wolf Restoration and Management Plan (CPW 2023b, entire) development is broadly based and includes a diverse array of stakeholders in the State, which has helped to address potential adverse effects to gray wolves through Federal, State, or private actions. Therefore, Federal, State, or private actions and activities in Colorado that are ongoing and expected to continue are not likely to have significant adverse effects on gray wolves within the NEP area.

Experimental Population Regulation Requirements

Our regulations at 50 CFR 17.81(c) include a list of what we should provide in regulations designating experimental populations under section 10(j) of the Act. We explain what our regulations include and provide our rationale for those regulations, below.

Means To Identify the Experimental Population

Our regulations require that we provide appropriate means to identify the experimental population, which may include geographic locations, number of individuals to be released, anticipated movements, and other information or criteria. The Colorado NEP area encompasses the entire State. As discussed below, we conclude that after initial releases, any gray wolves found in Colorado will, with a high degree of likelihood, have originated from and be members of the NEP. However, we recognize that absent identifying tags or collars, it may be very difficult for members of the public to easily determine the origin of any individual gray wolf. Therefore, we will use geographic location to identify members of the NEP. As such, any gray wolf within the State of Colorado will be considered part of the NEP regardless of its origin. Similarly, any wolf outside of the State will take on the status of that location. For example, a wolf moving from Wyoming into Colorado will take on the NEP status, whereas a wolf moving from Colorado into Wyoming will take on a not-listed status, or endangered status if it moves into any other adjacent State.

By the end of 2022, a minimum count of two wolves were known to occupy Colorado and do not constitute a population (see *Historical and Current Range,* above). While an adult female wolf dispersed from Wyoming to Colorado in 2019 to form half of the first reproductively active pack in the State in recent history, the origins of her mate are unknown. It is likely the male dispersed from the Greater Yellowstone area (approximately 480 km (300 miles) north and west of their current location), but his exact origin is uncertain (CPW 2021a, entire). The mean dispersal distance of male wolves in the NRM is 98.1 km (60 miles) (Jimenez et al. 2017, p. 585). The nearest known pack in Wyoming is more than 200 km (124 miles) from the Colorado border, which is more than two times the average dispersal distance for gray wolves. In addition, Wyoming manages gray wolves in northwestern Wyoming via a trophy management area, which restricts the number of gray wolves that can be harvested in that area. The southern extent of the trophy management area generally coincides with the southern extent of the gray wolf current range in the NRM (figure 1, above). Outside of the trophy management area, wolves are managed as predators and can be harvested at any time without a license and with no harvest limit. Gray wolf packs are unlikely to persist long term in portions of Wyoming where they are designated as predatory animals (85 FR 69778, November 3, 2020), which further limits the ability for individuals to enter Colorado from Wyoming.

Despite these challenges, it is possible that gray wolves dispersing from the NRM population could successfully enter the NEP. However, these movements would likely be infrequent given the NEP's distance from existing populations, and the normal dispersal distances for gray wolves. Additionally, the small numbers of individuals likely to occupy the NEP following the release and the sizable distances between populations makes any potential interaction between individuals or a merging of populations highly unlikely. Further, even if gray wolves from the NRM or other populations were to disperse into the NEP, the presence of one or a few individual dispersing gray wolves would not constitute a population, as described above.

Therefore, gray wolves reintroduced into Colorado will be wholly geographically separate from the delisted portion of the NRM population as well as the remainder of the currently listed 44-State entity. Based on this geographic separation, we conclude that any gray wolves found in Colorado after the initial release will, with a high degree of likelihood, be members of the NEP; therefore, we conclude that geographic location is an appropriate means to identify members of the NEP.

As noted in *Release Procedures,* above, CPW plans to fit individual animals reintroduced to the Colorado NEP with GPS collars or a mix of GPS and VHF collars, with GPS preferred in the early stages of the reintroduction effort. Reintroduced wolves fitted with radio telemetry collars and other identifiable marks prior to release will enable CPW to determine if animals within Colorado are members of the reintroduced NEP and not extant wolves from other populations (*e.g.,* the delisted NRM population). However, as reintroduced wolves begin to reproduce and disperse from Colorado packs, wolf abundance and distribution will increase in Colorado and the ability to capture and mark a high proportion of the population will decline. Given the challenges associated with marking a high number of wolves as the population increases and the distance from known packs in Wyoming and other populations of gray wolves, we will consider all gray wolves found in the State of Colorado to be members of the NEP.

Is the experimental population essential or nonessential?

When we establish experimental populations under section 10(j) of the Act, we must determine whether or not that population is essential to the continued existence of the species. This determination is based solely on the best scientific and commercial data available. Our regulations (50 CFR 17.80(b)) state that an experimental population is considered essential if its loss would be likely to appreciably reduce the likelihood of survival of that species in the wild. We are designating the population of gray wolves in Colorado as nonessential for the following reason.

Populations of gray wolves within the 44-state listed entity include the Great Lakes metapopulation and growing populations in California, Oregon, and Washington. Multiple large, growing, or stable metapopulations of gray wolves inhabiting separate and ecologically diverse areas ensure that the survival of the listed species does not rely on any single population. Therefore, the loss of the Colorado NEP would not be likely to appreciably reduce the likelihood of survival of the species in the wild, and we find that the Colorado NEP is not essential to the continued existence of the species.

Management Restrictions, Protective Measures, and Other Special Management

We have included management measures to address potential conflicts between wolves and humans and wolves and livestock. Management of the nonessential experimental population would allow gray wolves in the NEP to be hazed, killed, or relocated by the Service or our designated agent(s) for livestock depredations. Under special conditions, the public may harass or kill wolves in the act of attacking livestock (defined below). We have also included an exception to allow nonlethal and lethal management of gray wolves that are having an unacceptable impact to ungulate herds or populations on Tribal lands (defined below). This exception requires a science-based proposal that must, at a minimum, include the following information: (1) the basis of ungulate population or herd management objectives; (2) data indicating that the ungulate herd is below management objectives; (3) what data indicate that wolves are a major cause of the ungulate population decline; (4) why wolf removal is a warranted solution to help restore the ungulate herd to management objectives; (5) the level and duration of wolf removal being proposed; (6) how ungulate population response to wolf removal will be measured and control actions adjusted for effectiveness; and (7) demonstration that attempts were and are being made to address other identified major causes of ungulate herd or population declines or of Tribal government commitment to implement possible remedies or conservation measures in addition to wolf removal.

The proposal must be subjected to both public and peer review prior to it being finalized and submitted to the Service for review. At least three independent peer reviewers with relevant expertise in the subject matter that are not staff of the Tribe submitting the proposal must be used to review the proposal. Upon Service review, and before wolf removals can be authorized, the Service will evaluate the information provided by the requesting Tribe and provide a written determination to the requesting Tribal game and fish agency on whether such actions are scientifically based and warranted.

As the lead agency for reintroduction efforts for gray wolves in Colorado, CPW will coordinate with the Service on releases, monitoring, and other tasks as needed to ensure successful reintroduction of the species to the State. Definitions pertaining to special management provisions are listed below:

Depredating wolves—Gray wolves that have been confirmed by the Service or our designated agent as having depredated on livestock at least once within the last 30 days, and are routinely present and present a significant risk to the health and safety of livestock.

Designated agent—An employee of a Federal, State, or Tribal agency that is authorized or directed by the Service to conduct gray wolf management consistent with this rule.

The State of Colorado and Tribes within the State with wolf management plans also may become designated agents by submitting a request to the Service to establish a memorandum of agreement (MOA) under this rule. Once accepted by the Service, the MOA may allow the State of Colorado or Tribes within the State to assume lead authority for wolf conservation and management within their respective jurisdictions and to implement the portion of their State or Tribal wolf management plans that does not exceed the exceptions provided in this rule. The Service oversight (aside from Service law enforcement investigations) under an MOA is limited to monitoring compliance with this rule, issuing written authorizations for wolf take on reservations without wolf management plans, and an annual review of the State or Tribal program to ensure consistency with this rule. Under either a cooperative agreement or an MOA, no management outside the provisions of this rule is allowed unless we solicit additional public comment, and this rule is modified accordingly.

Incidental take—Experimental population rules contain specific prohibitions and exceptions regarding the taking of individual animals under the Act. These rules are compatible with most routine human activities in the NEP area (*e.g.,* resource monitoring, invasive species management, and research; see *How Will the NEP Further the Conservation of the Species?* above). Section 3(19) of the Act defines ''take'' as ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.'' ''Incidental take'' is further defined as take that is incidental to, and

not the purpose of, the carrying out of an otherwise lawful activity. See table 1 below for additional details on incidental take of gray wolves within the NEP area.

Intentional harassment—The deliberate and pre-planned harassment of wolves, including by less-than-lethal munitions that are designed to cause physical discomfort and temporary physical injury but not death. The term does not apply if there is evidence of unusual attractants or artificial or intentional feeding.

Interagency consultation—For purposes of section 7(a)(2) of the Act, section 10(j) of the Act and our regulations (at 50 CFR 17.83) provide that nonessential experimental populations are treated as species proposed for listing under the Act except on National Park Service and National Wildlife Refuge System lands, where they are treated as threatened species for the purposes of section 7(a)(2) of the Act. Where actions may affect gray wolves within units of the National Wildlife Refuge system or National Park Service in Colorado the Service will coordinate with the National Park Service and National Wildlife Refuge system to address their section 7(a)(2) obligations.

In the act of attacking—The actual biting, wounding, grasping, or killing of livestock or working dogs, or chasing, molesting, or harassing by wolves that would indicate to a reasonable person that such biting, wounding, grasping, or killing of livestock or dogs is likely to occur at any moment. This definition does not apply if there is evidence of unusual attractants or artificial or intentional feeding.

Landowner—An owner or lessee of private land, or their immediate family members, or the owner's employees, contractors, or volunteers who are currently employed to actively work on that private land. In addition, the owners (or their employees or contractors) of livestock that are currently and legally grazed on that private land and other leaseholders on that private land (such as outfitters or guides who lease hunting rights from private landowners), are considered landowners on that private land for the purposes of this regulation. Private land, under this rule, also includes all non-Federal land and land within Tribal reservations. Individuals legally using Tribal lands are considered landowners for the purposes of this rule.

Livestock—Cattle, sheep, pigs, horses, mules, goats, domestic bison, and herding and guarding animals (alpacas, llamas, donkeys, and certain breeds of dogs commonly used for herding or guarding livestock). Livestock excludes dogs that are not being used for livestock guarding or herding.

Livestock producer—A person who is actively engaged in farming/ranching and receives income from the production of livestock.

Non-injurious—Does not cause either temporary or permanent physical damage or death.

Opportunistic harassment—Harassment without the conduct of prior purposeful actions to attract, track, wait for, or search out the wolf. Opportunistic harassment includes scaring wolves with noise (*e.g.,* yelling or shooting firearms into the air), movement (*e.g.,* running or driving toward the wolf), or objects (*e.g.,* throwing a rock at a wolf or releasing bear pepper spray).

Private land—All land other than that under Federal Government ownership and administration and including Tribal reservations.

Public land—Federal land such as that administered by the National Park Service, U.S. Fish and Wildlife Service, Bureau of Land Management, USDA Forest Service, Bureau of Reclamation, Department of Defense, or other agencies with the Federal Government.

Public land permittee—A person or that person's employee who has an active, valid Federal land-use permit to use specific Federal lands to graze livestock or operate as an outfitter or guiding business that uses livestock. This definition does not include private individuals or organizations who have Federal permits for other activities on public land such as collecting firewood, mushrooms, antlers, or Christmas trees, or logging, mining, oil or gas development, or other uses that do not require livestock. In recognition of the special and unique authorities of Tribes and their relationship with the U.S. Government, for the purposes of this rule, the definition includes Tribal members who legally graze their livestock on ceded public lands under recognized Tribal treaty rights.

Relocation—Capture and movement to another location within the NEP.

Remove—Place in captivity or kill.

Research—Scientific studies resulting in data that will lend to enhancement of the survival of gray wolves.

Rule—''This rule'' in the regulatory text refers to the NEP regulations.

Tribal land—any lands where title is either held in trust by the United States for the benefit of an Indian Tribe or individual Indian or held by an Indian Tribe or individual Indian subject to restrictions by the United States against alienation (*i.e.,* sale or transfer).

Unacceptable impact—Tribally determined decline in a wild ungulate population or herd, where wolf predation is a major cause of the population or herd not meeting established Tribal management goals on Tribal land. The Tribal determination must be peer-reviewed and reviewed and commented on by the public prior to a final, written determination by the Service that an unacceptable impact has occurred and that wolf removal will benefit the affected ungulate herd or population.

Working dogs—Guard or herding dogs used in livestock production.

Wounded—Exhibiting scraped or torn hide or flesh, bleeding, or other evidence of physical damage caused by a wolf or wolves.

TABLE 1—ALLOWABLE FORMS OF TAKE FOR GRAY WOLVES IN THE COLORADO NEP AREA

Take provision	Description of provision in the experimental population rule
Take in defense of human life	Any person may take a wolf in defense of the individual's life or the life of another person. The unauthorized taking of a wolf without demonstration of an immediate and direct threat to human life may be referred to the appropriate authorities for prosecution.
Agency take of wolves determined to be a threat to human life and safety.	The Service, or our designated agents, may promptly remove (that is, place in captivity or kill) any wolf determined by the Service or designated agent to be a threat to human life or safety.
Opportunistic harassment	Anyone may conduct opportunistic harassment of any gray wolf in a non-injurious manner at any time. Opportunistic harassment must be reported to the Service or our designated agent within 7 days.

TABLE 1—ALLOWABLE FORMS OF TAKE FOR GRAY WOLVES IN THE COLORADO NEP AREA—Continued

Take provision	Description of provision in the experimental population rule
Intentional harassment	After the Service, or our designated agent, has confirmed wolf activity on private land or on a public land grazing allotment, the Service or our designated agent may issue written take authorization valid for not longer than 1 year to any landowner or public land permittee to intentionally harass wolves in a non-lethal, injurious manner. The harassment must occur in the area and under the conditions as specifically identified in the written take authorization. Intentional harassment must be reported to the Service or a designated agent within 7 days. This exception does not apply if there is evidence of unusual attractants or artificial or intentional feeding.
Taking wolves ''in the act of attacking'' livestock on PRIVATE land.	Consistent with State or Tribal requirements, any landowner may take (injure or kill) a gray wolf in the act of attacking (wounding, harassing, molesting, or killing) livestock or working dogs on their private land. Any wolf taken in the act must be reported to the Service or our designated agent within 24 hours. We will allow additional reasonable time if access to the site is limited. The carcass of any wolf taken and surrounding area must not be disturbed in order to preserve physical evidence that the livestock or working dogs were recently attacked by a wolf or wolves. The Service or our designated agent must be able to confirm that the livestock or dog were wounded, harassed, molested, or killed by a wolf or wolves. The taking of any wolf without such evidence may be referred to the appropriate authorities for prosecution. This exception to the prohibition on take does not apply if there is evidence of unusual attractants or artificial or intentional feeding.
Taking wolves ''in the act of attacking'' livestock on PUBLIC land.	Consistent with State or Tribal requirements, any livestock producer and public land permittee who is legally using public land under a valid Federal land-use permit may take a gray wolf in the act of attacking their livestock or working dogs on the person's allotment or other area authorized for their use without prior written authorization from the Service. The Service or our designated agent must be able to confirm that the livestock or working dogs were wounded, harassed, molested, or killed by a wolf or wolves. The carcass of any wolf taken and the area surrounding it must not be disturbed to preserve physical evidence that the take was conducted according to this rule. Any person legally present on public land may immediately take a wolf that is in the act of attacking the individual's stock animal or working dog, provided conditions noted in taking of wolves in the act on private land are met. Any take or method of take on public land must be consistent with the rules and regulations on those public lands. Any lethal or injurious take must be reported to the Service or a designated agent within 24 hours. We will allow additional reasonable time if access to the site is limited. This exception to the prohibition on take does not apply if there is evidence of unusual attractants or artificial or intentional feeding.
Additional taking by private citizens on their PRIVATE land.	At the Service's or our designated agents' direction, the Service or designated agent may issue a ''depredation'' written take authorization of limited duration (45 days or less) to a landowner or their employees to take up to a specified (by the Service or our designated agent) number of wolves on their private land if: (1) The landowner has had at least one depredation by wolves on livestock that has been confirmed by the Service or our designated agent within the last 30 days; and (2) the Service or our designated agent has determined that depredating wolves are routinely present on the private land and present a significant risk to the health and safety of livestock; and (3) the Service or our designated agent has authorized lethal removal of wolves from that same private land. These authorizations may be terminated at any time once threats have been resolved or minimized. Any lethal or injurious take must be reported to the Service or a designated agent within 24 hours. We will allow additional reasonable time if access to the site is limited. This exception does not apply if there is evidence of unusual attractants or artificial or intentional feeding.
Additional taking by grazing permittees on PUBLIC land.	At the Service's or our designated agents' direction, the Service or designated agent may issue a ''depredation'' written take authorization of limited duration (45 days or less) to a public land grazing permittee to take up to a specified (by the Service or our designated agent) number of wolves on that permittee's active livestock grazing allotment if: (1) The grazing allotment has had at least one depredation by wolves on livestock that has been confirmed by the Service or our designated agent within the last 30 days; and (2) the Service or our designated agent has determined that depredating wolves are routinely present on that allotment and present a significant risk to the health and safety of livestock; and (3) the Service or our designated agent has authorized lethal removal of wolves from that same allotment. These authorizations may be terminated at any time once threats have been resolved or minimized. Any take or method of take on public land must be consistent with the rules and regulations on those public lands. Any lethal or injurious take must be reported to the Service or a designated agent within 24 hours. We will allow additional reasonable time if access to the site is limited. This exception does not apply if there is evidence of unusual attractants or artificial or intentional feeding.
Agency take of wolves that depredate livestock.	The Service or our designated agent may carry out harassment, nonlethal control measures, relocation, placement in captivity, or lethal control of depredating wolves. The Service or our designated agent will consider: (1) Evidence of wounded livestock or working dogs or remains of livestock or working dogs that show that the injury or death was caused by wolves, or evidence that wolves were in the act of attacking livestock or working dogs; (2) the likelihood that additional wolf-caused losses or attacks may occur if no control action is taken; (3) evidence of unusual attractants or artificial or intentional feeding of wolves; and (4) evidence that animal husbandry practices recommended in approved allotment plans and annual operating plans were followed.
Incidental take	Any person may take a gray wolf if the take is incidental to an otherwise lawful activity, if reasonable due care was practiced to avoid such taking, and such taking is reported within 24 hours. We will allow additional reasonable time if access to the site is limited. Shooting a wolf as a result of mistaking it for another species is not considered incidental take and may be referred to the appropriate authorities for prosecution.
Permits for recovery actions that include take of gray wolves.	Permits are available and required, except as otherwise allowed by this rule, for scientific purposes, enhancement of propagation or survival, educational purposes, or other purposes consistent with the Act (50 CFR 17.32).

TABLE 1—ALLOWABLE FORMS OF TAKE FOR GRAY WOLVES IN THE COLORADO NEP AREA—Continued

Take provision	Description of provision in the experimental population rule
Additional taking provisions for agency employees and our designated agents.	Any Service employee or our designated agent may take a gray wolf from the NEP: (1) For take related to the release, tracking, monitoring, recapture, and management for the NEP; (2) to aid or euthanize sick, injured, or orphaned wolves or transfer to a licensed veterinarian for care; (3) to dispose of a dead specimen; (4) to salvage a dead specimen that may be used for scientific study; (5) to aid in law enforcement investigations involving wolves (collection of specimens for necropsy, etc.); or (6) to remove wolves with abnormal physical or behavioral characteristics, as determined by the Service or our designated agent, to prevent these gray wolves from passing on or teaching those traits to other wolves.
Take of gray wolves that are contributing to unacceptable impacts to wild ungulate populations or herds on Tribal land.	This would allow nonlethal and/or lethal management of gray wolves that are having an unacceptable impact to wild ungulate herds or populations on Tribal lands. This exception requires Tribes to develop a science-based proposal that must, at a minimum, include the following information: (1) the basis of ungulate population or herd management objectives; (2) data indicating that the ungulate herd is below management objectives; (3) data indicating that wolves are a major cause of the ungulate population decline; (4) why wolf removal is a warranted solution to help restore the ungulate herd to management objectives; (5) the level and duration of wolf removal being proposed; (6) how ungulate population response to wolf removal will be measured and control actions adjusted for effectiveness; and (7) demonstration that attempts were and are being made to address other identified major causes of ungulate herd or population declines or of Tribal government commitment to implement possible remedies or conservation measures in addition to wolf removal. The proposal must be subjected to both public and peer review prior to it being finalized and submitted to the Service for review. At least three independent peer reviewers with relevant expertise in the subject matter that are not staff of the Tribe submitting the proposal must be used to review the proposal. Upon Service review, and before wolf removals can be authorized, the Service will evaluate the information provided by the requesting Tribe and provide a written determination to the requesting Tribal game and fish agency on whether such actions are scientifically based and warranted.

Review and Evaluation of the Success or Failure of the NEP

CPW plans to use ground and aerial monitoring techniques to document wolf reproductive success, abundance, and distribution in Colorado post-release. This information will be summarized in an annual report by CPW that describes wolf conservation and management activities that occurred in Colorado each calendar or biological year to evaluate progress toward achieving the State of Colorado's downlisting and recovery criteria. A copy of the report will be submitted annually to the Service by June 30th and posted on CPW's website. The annual report may include, but not be limited to, post-release wolf movements and behavior; wolf minimum counts or abundance estimates; reproductive success and recruitment; territory use and distribution; cause-specific wolf mortalities; and a summary of wolf conflicts and associated management activities to minimize wolf conflict risk. For additional details, please see CPW 2021b (entire) and *Release Procedures,* above.

The Service will evaluate Colorado's wolf reintroduction and management program in an annual summary report. Additionally, 5 years after the last reintroductions are completed, the Service will evaluate whether the wolf population is meeting the State's recovery goals and conservation of the species. During this evaluation, we will assess the reintroduction program and coordinate with CPW if it is determined that modifications to reintroduction protocols are necessary. We believe that 5 years after the reintroductions is a reasonable timeline for this evaluation because that timeline would allow for evaluation of the success of the management program and of wolf population growth and abundance in order to assess progress toward achieving the State of Colorado's recovery goals. If modifications to wolf monitoring and management activities are needed, the Service will coordinate closely with CPW to ensure progress toward achieving recovery goals while concurrently minimizing wolf-related conflicts in Colorado.

Other Considerations

Above, we considered potential effects of the release on wild populations of the delisted NRM potential donor populations. We also considered potential effects of the release on the Mexican wolf. The number of gray wolves in Colorado could continue to grow and expand, which could increase the likelihood that gray wolves in Colorado disperse far enough south to encounter Mexican wolves. The timing and extent of any potential future contact are uncertain and difficult to project, but if contact were to occur, interbreeding is a concern for the Mexican wolf. If gray wolves come to occupy Mexican wolf recovery areas, these physically larger wolves are likely to dominate smaller Mexican wolves and quickly occupy breeding positions, as will their hybrid offspring. Hybrid population(s) thus derived will not contribute towards recovery of Mexican wolves because they will significantly threaten integrity of the listed entity (Odell et al. 2018, entire). However, potential inbreeding would be unlikely to have significant effects on the gray wolf, given the narrow geographic range in which such contact would likely occur relative to the species' overall range. Additionally, we do not intend to initiate or allow adaptive introgression between gray wolves and Mexican wolves as part of the genetic management of Mexican wolves (87 FR 39357, July 1, 2022). To help minimize interactions and protect Mexican wolf genetic integrity, we have simultaneously issued a section 10(a)(1)(A) permit to be held by the Service, which would authorize our designated agents to assist in the capture and return of wolves originating from the Colorado NEP.

Findings

Based on the best scientific and commercial data available (in accordance with 50 CFR 17.81), we find that releasing gray wolves into the State of Colorado with the regulatory provisions in this rulemaking will further the conservation of the species in the currently listed 44-State entity. The NEP status is appropriate for the introduced population; the potential loss of the experimental population would not appreciably reduce the likelihood of the survival of the species in the 44-State listed entity since more than 4,600 wolves are distributed across at least 6 different States in the Western

United States and the western Great Lakes.

Required Determinations

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

Executive Order (E.O.) 14094 reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this final rule in a manner consistent with these requirements.

E.O. 12866, as reaffirmed by E.O. 13563 and E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

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

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

This rule is modeled after previous NEP designations in Idaho, Montana, and Wyoming that contributed to the recovery of gray wolves while allowing for the control and management of wolves that caused conflicts and economic impacts on livestock producers. The majority of gray wolves in the Western United States are part of the NRM population, which is no longer protected under the Act. Despite increased incidences of human-caused mortality in the NRM population after delisting, this population is stable to increasing.(Service 2020, pp. 14–19; 85 FR 69778, November 3, 2020).

The State of Colorado has recognized the utility of NEP designations in reintroducing gray wolves while addressing the concerns of local, State, and Tribal governments, as well as private entities, and engaged in an extensive stakeholder outreach process to develop a State management plan with broad-based support (CPW 2022). This process, which involved a Stakeholder Advisory Group comprising a diverse array of stakeholders such as agricultural producers, hunting guides, wolf conservation advocates, and other interests and a Technical Working Group comprising gray wolf experts, assisted in the formulation of an impact-based management matrix and the overall Colorado Gray Wolf Management and Restoration Plan.

The reduced restrictions on taking depredating wolves (see definition above under *Management Restrictions, Protective Measures, and Other Special Management*) in this rule, relative to endangered species that receive the full protections of sections 7 and 9 of the Act, will make the management of wolves easier and more effective, thus reducing the economic losses that result from depredation of wolves on livestock and guard animals and working dogs. Furthermore, a State program to compensate livestock producers who experience livestock losses caused by wolves is being developed and will be implemented upon CPW Commission approval. As a point of reference, compensation for livestock losses in Montana in 2021 totaled $103,815.95 (Parks et al. 2022, p. 19), and compensation in Wyoming for 2022 totaled $187,382.00 (WGFD et al. 2023, pp. 24). The potential effect on livestock producers in western States is very small, but more flexible wolf management will provide benefits to stakeholders and livestock producers by providing options to protect assets.

During the development of this final rule, we reviewed and evaluated all information submitted during the comment period on the proposed rule (88 FR 10258, February 17, 2023) that may pertain to our consideration of the probably incremental economic impacts of this NEP designation. Based on this information, we affirm our certification that this NEP designation under section 10(j) of the Act will not have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare statements of energy effects ''to the extent permitted by law'' when undertaking actions identified as significant energy actions (66 FR 28355, May 22, 2001). E.O. 13211 defines a ''significant energy action'' as an action that (i) is a significant regulatory action under E.O. 12866 (or any successor order, including most recently E.O. 14094 (88 FR 21879, April 11, 2023)); and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule is not a significant regulatory action under E.O. 12866 or 14094. Therefore, this action is not a significant energy action, and there is no requirement to prepare a statement of energy effects for this action.

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

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following finding:

(1) This rule will not produce a Federal mandate of $100 million or greater in any year (*i.e.,* it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act). This NEP designation for gray wolves in Colorado would not impose any additional management or protection requirements on the States or other entities. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7).

''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or Tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or Tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

(2) We do not believe that this rule will significantly or uniquely affect small governments because it would not impose a cost of $100 million or more in any given year on local or State governments or private entities and it would not place additional requirements on any city, county, or other local municipalities. Therefore, a small government agency plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have determined that this rule will not have significant implications concerning taking of private property by the Federal Government. This rule will substantially advance a legitimate government interest (conservation of a listed species) and will not present a bar to all reasonable and expected beneficial use of private property. Additionally, because of the regulatory flexibility provided by NEP designations under section 10(j) of the Act, the increased flexibility provided by this rule for State or Tribal-led gray wolf management will reduce regulatory restrictions on private lands and will result in minor positive economic effects for a small percentage of livestock producers. Therefore, we conclude that this rulemaking for the gray wolf does not pose significant taking implications.

Federalism—Executive Order 13132

In accordance with Executive Order 13132, this rule does not have significant federalism effects. This rule will not have substantial direct effects on the States, on the relationship between the States and the Federal Government, or on the distribution of power and responsibilities among the various levels of government. CPW requested that we undertake this rulemaking to support the conservation of wolves in the 44-State entity and in Colorado and to provide increased take authority to resolve gray wolf conflicts, which will assist with conservation of the species. No intrusion on State policy or administration is expected; roles or responsibilities of Federal or State governments will not change; and fiscal capacity will not be substantially affected. This rule operates to maintain the existing relationship between the States and the Federal Government and is being undertaken at the request of CPW. We cooperated with CPW and other State agencies in the preparation of this rule. Therefore, this rule does not have significant federalism effects or implications to warrant the preparation of a federalism assessment pursuant to the provisions of Executive Order 13132.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule would not unduly burden the judicial system and would meet the requirements of sections (3)(a) and (3)(b)(2) of the Order. We are designating the NEP in accordance with the provisions of the Act. To assist the public in understanding the NEP, this rule presents the areas of the NEP on a map and the rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule contains existing and new collections of information that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB previously reviewed the new information collection requirements contained in this rulemaking related to the establishment of an NEP of the gray wolf (*Canis lupus*) in the State of Colorado, under section 10(j) of the ESA and assigned OMB Control Number 1018–0189. OMB has previously approved the information collection requirements associated with permitting requirements associated with native endangered and threatened species, and experimental populations, and assigned OMB Control Number 1018–0094, ''Federal Fish and Wildlife Permit Applications and Reports—Native Endangered and Threatened Species; 50 CFR parts 10, 13, and 17'' (expires January 31, 2024).

Experimental populations established under section 10(j) of the Act, as amended, require information collection and reporting to the Service. We will collect information on the gray wolf NEP to help further the recovery of the species and to assess the success of the reintroduced populations. There are no forms associated with this information collection. The respondents notify us when an incident occurs, so there is no set frequency for collecting the information. Other Federal agencies provide us with the vast majority of the information on experimental populations under cooperative agreements for the conduct of the recovery programs. However, the public also provides some information to us. The new information collection

requirements identified below require approval by OMB:

1. *Appointment of designated agent*—A designated agent is an employee of a Federal, State, or Tribal agency that is authorized or directed by the Service to conduct gray wolf management. A prospective designated agent submits a letter to the Service requesting designated agent status. The letter includes a proposal for the work to be completed, a list of individuals that may perform the work, and a resume (or similar) demonstrating qualifications of each individual to competently perform the work. The Service will then respond to the requester with a letter authorizing them to complete the work.

2. *Request for written take authorization*—After receiving confirmation of wolf activity on private land or on a public land grazing allotment, we or the designated agent may issue written take authorization valid for not longer than 1 year, with appropriate conditions, to any landowner or public land permittee to intentionally harass wolves. The harassment must occur in the area and under the conditions as specifically identified in the written take authorization.

3. *Request for ''depredation'' written take authorization*—The Service or designated agent may issue a ''depredation'' written take authorization of limited duration (45 days or fewer) to a landowner or their employees, or to a public land grazing permittee, to take up to a specified (by the Service or our designated agent) number of wolves.

4. *Reporting requirements*—Except as otherwise specified in this rule or in an authorization, any take of a gray wolf must be reported to the Service, or our designated agent as follows (additional reasonable time will be allowed if access to the site is limited):

a. *Lethal take* must be reported within 24 hours. We will allow additional reasonable time if access to the site is limited.

b. *Opportunistic or intentional harassment* must be reported within 7 days.

c. Gray wolves *taken into captivity for care or to be euthanized* must be reported to the Service within 24 hours, or as soon as reasonably appropriate.

5. *Annual report*—To evaluate progress toward achieving State downlisting and delisting criteria, CPW will summarize monitoring information in an annual report. The report, due by June 30 of each year, will describe wolf conservation and management activities that occurred in Colorado for as long as the gray wolf is federally listed during any portion of a calendar or biological year. The annual report will include, but not be limited to:

- post-release wolf movements and behavior;
- wolf minimum counts or abundance estimates;
- reproductive success and recruitment;
- territory use and distribution;
- cause-specific wolf mortalities; and
- a summary of wolf conflicts and associated management activities to minimize wolf conflict risk.

6. *Recovery or reporting of dead individuals and specimen collection from experimental populations*—This type of information is for the purpose of documenting incidental or authorized scientific collection. Specimens are to be retained or disposed of only in accordance with directions from the Service. Most of the contacts with the public deal primarily with the reporting of sightings of experimental population animals, or the inadvertent discovery of an injured or dead individual.

7. *Proposal—Take of Gray Wolves on Tribal Lands (NEW in Final Rule)*—The exception to allow take of gray wolves that are contributing to unacceptable impacts to wild ungulate population or herds on Tribal land requires Tribes to develop a science-based proposal that must, at a minimum, include the following information:

- The basis of ungulate population or herd management objectives;
- Data indicating that the ungulate herd is below management objectives;
- Data indicating that wolves are a major cause of the ungulate population decline;
- Why wolf removal is a warranted solution to help restore the ungulate herd to management objectives;
- The level and duration of wolf removal being proposed;
- How ungulate population response to wolf removal will be measured and control actions adjusted for effectiveness; and
- Demonstration that attempts were and are being made to address other identified major causes of ungulate herd or population declines or of Tribal government commitment to implement possible remedies or conservation measures in addition to wolf removal. The proposal must be subjected to both public and peer review prior to it being finalized and submitted to the Service for review. At least three independent peer reviewers with relevant expertise in the subject matter that are not staff of the Tribe submitting the proposal must be used to review the proposal. Upon Service review, and before wolf removals can be authorized, the Service will evaluate the information provided by the requesting Tribe and provide a written determination to the requesting Tribal game and fish agency on whether such actions are scientifically based and warranted.

We will use the information described above to assess the effectiveness of control activities and develop means to reduce problems with livestock where depredation is a problem. Service recovery specialists use the information to determine the success of reintroductions in relation to established recovery plan goals for the threatened and endangered species involved.

Title of Collection: Endangered and Threatened Wildlife, Experimental Populations—Colorado Gray Wolf (50 CFR 17.84).

OMB Control Number: 1018–0189.

Form Numbers: None.

Type of Review: New.

Respondents/Affected Public: Individuals; private sector; and State/local/Tribal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually for annual report and on occasion for other requirements.

Total Estimated Annual Non-Hour Burden Cost: None.

Requirement	Number of annual respondents	Number of annual responses each	Total annual responses	Average completion time	Total annual burden hours
Appointment of Designated Agent:					
Individuals	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Private Sector	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
State/Local/Tribal Gov't	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Request for Written Take Authorization:					
Individuals	1	1	1	30 min (reporting); 30 min (recordkeeping)	1

Requirement	Number of annual respondents	Number of annual responses each	Total annual responses	Average completion time	Total annual burden hours
Private Sector	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
State/Local/Tribal Gov't	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Request for "Depredation" Written Take Authorization:					
Individuals	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Private Sector	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
State/Local/Tribal Gov't	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Reporting Requirement—Lethal Take:					
Individuals	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Private Sector	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
State/Local/Tribal Gov't	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Reporting Requirement—Opportunistic or Intentional Harassment:					
Individuals	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Private Sector	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
State/Local/Tribal Gov't	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Reporting Requirement—Captivity for Care or to be Euthanized:					
Individuals	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Private Sector	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
State/Local/Tribal Gov't	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Annual Report:					
Individuals	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Private Sector	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
State/Local/Tribal Gov't	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Notification—Recovery or Reporting of Dead Specimen and Specimen Collection:					
Individuals	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Private Sector	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
State/Local/Tribal Gov't	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Proposal—Take of Gray Wolves on Tribal Lands (NEW in Final Rule):					
State/Local/Tribal Gov't	1	1	1	30 min (reporting); 30 min (recordkeeping)	1
Totals	25		25		25

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on any aspect of this information collection, including:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

We will accept and consider all public comments concerning the information collection requirements received in response to this final rule. Send your written comments and suggestions on this information collection to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803 (mail); or *Info_Coll@fws.gov* (email). Please reference ''OMB Control Number 1018–BG79'' in the subject line of your comments.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have prepared a final environmental impact statement (FEIS) pursuant to the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with this rule to designate the Colorado nonessential experimental population of gray wolves. The purpose of the FEIS is to identify and disclose the environmental consequences resulting from the designation of the gray wolf in Colorado. The FEIS is an outgrowth of the public scoping process we conducted from July 21, 2022, to August 22, 2022, and the public and peer review comments we received on the draft environmental impact statement (DEIS) (see 88 FR 10318, February 17, 2023), and our February 17, 2023, proposed rule (88 FR 10258). We used the FEIS, which we announced in the **Federal Register** on September 19, 2023 (88 FR 64399), to inform our final decision for this rulemaking.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes on a government-to-government basis. We have considered possible effects of this rule on federally recognized Indian Tribes. In accordance with Secretaries'

Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. In July 2022, we sent notification letters to the Native American Tribes within and adjacent to the NEP about this rule, and to determine their interest in participating in Tribal consultation under Secretaries' Order 3206 for this action. We invited the Ute Mountain Ute and the Southern Ute Indian Tribes to serve as cooperating agencies in the development of the environmental impact statement. In October 2022, we provided an informational webinar to the interested Tribes and in January 2023, we participated in government-to-government consultation with the Southern Ute Indian Tribe. In February 2023, we participated in an informational meeting with the Ute Mountain Ute Indian Tribe. If future activities resulting from this rule may affect Tribal resources, the Service will communicate and consult on a government-to-government basis with any affected Native American Tribes in order to find a mutually agreeable solution.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Colorado Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this rule are the staff members of the Colorado Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

Accordingly, we hereby amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11, in paragraph (h), by revising the entry for ''Wolf, gray'' under Mammals in the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
		MAMMALS		
*	*	* * *	*	*
Wolf, gray	*Canis lupus*	U.S.A.: All of AL, AR, CA, CT, DE, FL, GA, IA, IN, IL, KS, KY, LA, MA, MD, ME, MI, MO, MS, NC, ND, NE, NH, NJ, NV, NY, OH, OK, PA, RI, SC, SD, TN, TX, VA, VT, WI, and WV; and portions of AZ, NM, OR, UT, and WA as follows: (1) Northern AZ (that portion north of the centerline of Interstate Highway 40); (2) Northern NM (that portion north of the centerline of Interstate Highway 40); (3) Western OR (that portion of OR west of the centerline of Highway 395 and Highway 78 north of Burns Junction and that portion of OR west of the centerline of Highway 95 south of Burns Junction); (4) Most of UT (that portion of UT south and west of the centerline of Interstate Highway 84 and that portion of UT south of Interstate Highway 80 from Echo to the UT/WY Stateline); and (5) Western WA (that portion of WA west of the centerline of Highway 97 and Highway 17 north of Mesa and that portion of WA west of the centerline of Highway 395 south of Mesa); Mexico.	E	32 FR 4001, 3/11/1967; 41 FR 24062, 6/14/1976; 43 FR 9607, 3/9/1978; 73 FR 75356, 12/11/2008; 74 FR 47483, 9/16/2009; 80 FR 9218, 2/20/2015; 50 CFR 17.95(a).[CH]
Wolf, gray [Colorado XN].	*Canis lupus*	U.S.A. (CO)	XN	88 FR [*Insert* **Federal Register** *page where the document begins*], 11/8/2023; 50 CFR 17.84(n).[10j]
Wolf, gray	*Canis lupus*	U.S.A. (MN)	T	43 FR 9607, 3/9/1978; 50 CFR 17.40(d);[4(d)] 50 CFR 17.95(a).[CH]
*	*	* * *	*	*

■ 3. Amend § 17.84 by adding paragraph (n) to read as follows:

§ 17.84 Special rules—vertebrates.

* * * * *

(n) Wolf, gray (*Canis lupus*). (1) *Purpose.* The regulations in this paragraph (n) set forth the provisions of a rule to establish an experimental population of gray wolves. The Service finds that establishment of an experimental population of gray wolves as described in this paragraph (n) will further the conservation of the species.

(2) *Determinations.* The gray wolves identified in paragraph (n)(3) of this section constitute a nonessential experimental population (NEP) under § 17.81(c)(2). These wolves will be managed in accordance with the provisions of this rule in the boundaries of the NEP area within the State of Colorado or any Tribal reservation found in the State that has a wolf management plan, as further provided in this rule. Furthermore, the State of Colorado or any Tribe within the State that has a wolf management plan consistent with this rule can request to assume the lead authority for wolf management under this rule within the borders of the NEP area in the State or reservation as set forth in paragraph (n)(10) of this section.

(3) *Designated area.* The Colorado NEP area encompasses the entire State of Colorado. All gray wolves found in the wild within the boundary of the Colorado NEP area are considered nonessential experimental animals. Any gray wolf that is outside the Colorado NEP area, with the exception of wolves in the States of Idaho, Minnesota, Montana, Wyoming, and portions of the States of Oregon, Washington, and Utah, is considered endangered. Any wolf originating from the Colorado NEP area and dispersing beyond its borders may be managed by the wolf management regulations established for that area or may be returned to the Colorado NEP area.

(4) *Definitions.* Key terms used in this rule have the following meanings:

Depredating wolves—Gray wolves that have been confirmed by the Service or our designated agent as having depredated on livestock at least once within the last 30 days, and are routinely present and present a significant risk to the health and safety of livestock.

Designated agent—An employee of a Federal, State, or Tribal agency that is authorized or directed by the Service to conduct gray wolf management consistent with this rule.

Intentional harassment—The deliberate and pre-planned harassment of wolves, including by less-than-lethal munitions that are designed to cause physical discomfort and temporary physical injury but not death.

In the act of attacking—The actual biting, wounding, grasping, or killing of livestock or working dogs or chasing, molesting, or harassing by wolves that would indicate to a reasonable person that such biting, wounding, grasping, or killing of livestock or working dogs is likely to occur at any moment.

Landowner—Any of the following entities:

(A) An owner or lessee of private land, or their immediate family members, or the owner's employees, contractors, or volunteers who are currently employed to actively work on that private land.

(B) The owners, or their employees or contractors, of livestock that are currently and legally grazed on private land and herding and guarding animals (such as alpacas, llamas, or donkeys) and other leaseholders on private land, such as outfitters or guides who lease hunting rights from private landowners.

(C) Individuals legally using Tribal lands in the State of Colorado.

Livestock—Cattle, sheep, pigs, horses, mules, goats, domestic bison, and herding and guarding animals (alpacas, llamas, donkeys, and certain breeds of dogs commonly used for herding or guarding livestock). Livestock excludes dogs that are not being used for livestock guarding or herding.

Livestock producer—A person who is actively engaged in farming/ranching and receives income from the production of livestock.

Non-injurious—Does not cause either temporary or permanent physical damage or death.

Opportunistic harassment—Harassment without the conduct of prior purposeful actions to attract, track, wait for, or search out the wolf. Opportunistic harassment includes scaring wolves with noise (*e.g.,* yelling or shooting firearms into the air), movement (*e.g.,* running or driving toward the wolf), or objects (*e.g.,* throwing a rock at a wolf or releasing bear pepper spray).

Private land—All land other than that under Federal Government ownership and administration and including Tribal reservations.

Public land—Federal land such as that administered by the National Park Service, U.S. Fish and Wildlife Service, Bureau of Land Management, Bureau of Reclamation, U.S. Department of Agriculture's Forest Service, Department of Defense, or other agencies within the Federal Government.

Public land permittee—A person or that person's employee who has an active, valid Federal land-use permit to use specific Federal lands to graze livestock or operate an outfitter or guiding business that uses livestock and Tribal members who legally graze their livestock on ceded public lands under recognized Tribal treaty rights. This term does not include private individuals or organizations who have Federal permits for other activities on public land such as collecting firewood, mushrooms, antlers, or Christmas trees, logging, mining, oil or gas development, or other uses that do not require livestock.

Relocation—Capture and movement to another location.

Remove—Place in captivity or kill.

Research—Scientific studies resulting in data that will lend to enhancement of the survival of the gray wolf.

Rule—The regulations in this paragraph (n).

Tribal land—Any lands where title is either held in trust by the United States for the benefit of an Indian Tribe or individual Indian or held by an Indian Tribe or individual Indian subject to restrictions by the United States against alienation (*i.e.,* sale or transfer).

Unacceptable impact—Tribally determined decline in a wild ungulate population or herd where wolf predation is a major cause of the population or herd not meeting established Tribal management goals on Tribal land. The Tribal determination must be peer-reviewed and reviewed and commented on by the public prior to a final, written determination by the Service that an unacceptable impact has occurred and that wolf removal will benefit the affected ungulate herd or population.

Working dogs—Guard or herding dogs typically used in livestock production.

Wounded—Exhibiting scraped or torn hide or flesh, bleeding, or other evidence of physical damage caused by a wolf.

(5) *Allowable forms of take of gray wolves.* Take of gray wolves in the experimental population is allowed without a permit only in these specific circumstances: opportunistic harassment; intentional harassment; take in defense of human life; take to protect human safety; take by designated agents to remove depredating wolves; incidental take; take under any previously authorized permits issued by the Service; take per authorizations for employees of designated agents; take for research purposes; and take to protect livestock animals and working dogs. Consistent with the requirements of the State or

Tribe, take is allowed on private land. Take on public land is allowed as specified in paragraph (n)(5)(iv)(A) of this section. Other than as expressly provided by the regulations in this rule, all other forms of take are considered a violation of section 9 of the Act. Any wolf or wolf part taken legally must be turned over to the Service unless otherwise specified in this rule. Any take of wolves must be reported as set forth in paragraph (n)(6) of this section.

(i) *Opportunistic harassment.* Anyone may conduct opportunistic harassment of any gray wolf in a non-injurious manner at any time. Opportunistic harassment must be reported to the Service or a designated agent within 7 days as set forth in paragraph (n)(6) of this section.

(ii) *Intentional harassment.* After we or a designated agent have confirmed wolf activity on private land or a public land grazing allotment, we or the designated agent may issue written take authorization, with appropriate conditions, valid for not longer than 1 year to any landowner or public land permittee to intentionally harass wolves. The harassment must occur in the area and under the conditions as specifically identified in the written take authorization. Intentional harassment must be reported to the Service or a designated agent(s) within 7 days as set forth in paragraph (n)(6) of this section. The provisions in this paragraph (n)(5)(ii) do not apply if there is evidence of unusual attractants or artificial or intentional feeding.

(iii) *Take by landowners on their private land.* Landowners may take wolves on their private land in the following two additional circumstances:

(A) Consistent with State or Tribal requirements, any landowner may take a gray wolf in the act of attacking livestock or working dogs on private land (owned or leased), provided that there is no evidence of intentional baiting, feeding, or deliberate attractants of wolves. To preserve physical evidence that the livestock or working dogs were recently attacked by a wolf or wolves, the carcass of any wolf taken and surrounding area must not be disturbed. The Service or designated agent must be able to confirm that the livestock or dogs were wounded, harassed, molested, or killed by wolves. The take of any wolf without such evidence of a direct and immediate threat may be referred to the appropriate authorities for prosecution.

(B) The Service or designated agent may issue a ''depredation'' written take authorization of limited duration (45 days or fewer) to a landowner or their employees to take up to a specified (by the Service or our designated agent) number of wolves on their private land if:

(*1*) The landowner has had at least one depredation by wolves on livestock that has been confirmed by the Service or our designated agent within the last 30 days; and

(*2*) The Service or our designated agent has determined that depredating wolves routinely occur on the private land and present a significant risk to the health and safety of livestock; and

(*3*) The Service or our designated agent has authorized lethal removal of wolves from those same private lands.

(*4*) The authorizations set forth by this paragraph (n)(5)(iii)(B) may be terminated at any time once threats have been resolved or minimized.

(iv) *Take on public land.* Consistent with State or Tribal requirements, any livestock producer and public land permittee (see definitions in paragraph (n)(4) of this section) who is legally using public land under a valid Federal land-use permit may, without prior written authorization, take a gray wolf in the act of attacking livestock or working dogs on the person's allotment or other area authorized for the person's use.

(A) The Service or designated agent must be able to confirm that the livestock or working dog was wounded, harassed, molested, or killed by a wolf or wolves. To preserve physical evidence that the take was conducted according to this rule, the carcass of any wolf taken and the area surrounding it should not be disturbed. Any person legally present on public land may immediately take a wolf that is in the act of attacking the individual's livestock animal or working dog, provided conditions described in paragraph (n)(5)(iii)(A) of this section for private land (*i.e.,* ''in the act of attacking'') are met. Any take or method of take on public land must be consistent with the laws and regulations on those public lands.

(B) The Service or our designated agent may issue a ''depredation'' written take authorization of limited duration (45 days or fewer) to a public land grazing permittee to take up to a specified (by the Service or our designated agent) number of wolves on that permittee's active livestock grazing allotment if all of the following situations occur:

(*1*) The grazing allotment has had at least one depredation by wolves on livestock that has been confirmed by the Service or our designated agent within the last 30 days; and

(*2*) The Service or our designated agent has determined that depredating wolves routinely occur on that allotment and present a significant risk to the health and safety of livestock; and

(*3*) The Service or our designated agent has authorized lethal removal of wolves from that same allotment.

(*4*) The authorizations set forth by this paragraph (n)(5)(iv)(B) may be terminated at any time once threats have been resolved or minimized.

(*5*) Any take or method of take on public land must be consistent with the rules and regulations on those public lands.

(v) *Agency take of wolves that depredate livestock.* The Service or our designated agent may carry out harassment, nonlethal control measures, relocation, placement in captivity, or lethal control of depredating wolves. The Service or our designated agent will consider:

(A) Evidence of wounded livestock or working dogs or remains of livestock or working dogs that show that the injury or death was caused by wolves, or evidence that wolves were in the act of attacking livestock or working dogs;

(B) The likelihood that additional wolf-caused losses or attacks may occur if no control action is taken;

(C) Any evidence of unusual attractants or artificial or intentional feeding of wolves; and

(D) Evidence that animal husbandry practices recommended in approved allotment plans and annual operating plans were followed.

(vi) *Take in defense of human life.* Any person may take a gray wolf in defense of the individual's life or the life of another person. The taking of a wolf without an immediate and direct threat to human life may be referred to the appropriate authorities for prosecution.

(vii) *Take to protect human safety.* The Service or our designated agent may promptly remove any wolf that we or our designated agent determines to be a threat to human life or safety.

(viii) *Incidental take.* Take of a gray wolf is allowed if the take is accidental and/or incidental to an otherwise lawful activity and if reasonable due care was practiced to avoid such take and such take is reported within 24 hours as set forth at paragraph (n)(6) of this section. We may refer incidental take that does not meet these provisions to the appropriate authorities for prosecution. Shooters have the responsibility to identify their target before shooting. Shooting a wolf as a result of mistaking it for another species is not considered incidental take and may be referred to the appropriate authorities for prosecution.

(ix) *Take under permits.* Any person with a valid permit issued by the Service under 50 CFR 17.32, or our designated agent, may take wolves in the wild, pursuant to terms of the permit.

(x) *Additional take authorization for agency employees.* When acting in the course of official duties, any employee of the Service or a designated agent may take a wolf, when necessary, in regard to the release, tracking, monitoring, recapture, and management of the NEP or to:

(A) Aid or euthanize a sick, injured, or orphaned wolf and transfer it to a licensed veterinarian for care;

(B) Dispose of a dead specimen;

(C) Salvage a dead specimen that may be used for scientific study;

(D) Aid in law enforcement investigations involving wolves (collection of specimens for necropsy, etc.); or

(E) Remove wolves with abnormal physical or behavioral characteristics, as determined by the Service or our designated agent, from passing on or teaching those traits to other wolves.

(F) Such take must be reported to the Service as set forth in paragraph (n)(6) of this section, and specimens are to be retained or disposed of only in accordance with directions from the Service.

(xi) *Take of gray wolves that are contributing to unacceptable impacts to wild ungulate populations or herds on Tribal land.* This exception requires Tribes to develop a science-based proposal that must, at a minimum, include the following information:

(A) The basis of ungulate population or herd management objectives;

(B) Data indicating that the ungulate herd is below management objectives;

(C) Data indicating that wolves are a major cause of the ungulate population decline;

(D) Why wolf removal is a warranted solution to help restore the ungulate herd to management objectives;

(E) The level and duration of wolf removal being proposed;

(F) How ungulate population response to wolf removal will be measured and control actions adjusted for effectiveness; and

(G) Demonstration that attempts were and are being made to address other identified major causes of ungulate herd or population declines or of Tribal government commitment to implement possible remedies or conservation measures in addition to wolf removal.

(H) The proposal described in this paragraph (n)(5)(xi) must be subjected to both public and peer review prior to being finalized and submitted to the Service for review. Peer review must include at least three independent peer reviewers with relevant expertise in the subject matter who are not staff of the Tribe submitting the proposal. Before wolf removals can be authorized, the Service will evaluate the information in the proposal and provide a written determination to the requesting Tribal game and fish agency on whether such actions are scientifically based and warranted.

(xii) *Take for research purposes.* Permits are available and required, except as otherwise allowed by this rule, for scientific purposes, enhancement of propagation or survival, educational purposes, or other purposes consistent with the Act (50 CFR 17.32). Scientific studies should be reasonably expected to result in data that will lead to development of sound management of the gray wolf and to enhancement of its survival as a species.

(6) *Reporting requirements.* Except as otherwise specified in this rule or in an authorization, any take of a gray wolf must be reported to the Service or our designated agent as follows: Lethal take must be reported within 24 hours, and opportunistic or intentional harassment must be reported within 7 days. We will allow additional reasonable time if access to the site is limited.

(i) Report any take of wolves, including opportunistic harassment or intentional harassment, to U.S. Fish and Wildlife Service, Colorado Ecological Services Field Office Supervisor (134 Union Boulevard, Suite 670, Lakewood, Colorado 80225; *ColoradoES@fws.gov*), or a Service-designated agent of another Federal, State, or Tribal agency.

(ii) Unless otherwise specified in this paragraph (n), any wolf or wolf part taken legally must be turned over to the Service, which will determine the disposition of any live or dead wolves.

(7) *Prohibitions.* Take of any gray wolf in the NEP is prohibited, except as provided in paragraphs (n)(5) and (8) of this section. Specifically, the following actions are prohibited by this rule:

(i) No person shall possess, sell, deliver, carry, transport, ship, import, or export by any means whatsoever, any wolf or part thereof from the experimental population taken in violation of the regulations in this paragraph (n) or in violation of applicable State or Tribal fish and wildlife laws or regulations or the Act.

(ii) It is unlawful for any person to attempt to commit, solicit another to commit, or cause to be committed any offense defined in this paragraph (n).

(8) *Monitoring.* Gray wolves in the NEP area will be monitored by radio telemetry or other standard wolf population monitoring techniques as appropriate. Any animal that is sick, injured, or otherwise in need of special care may be captured by authorized personnel of the Service or our designated agent and given appropriate care. Such an animal will be released back into its respective area as soon as possible, unless physical or behavioral problems make it necessary to return the animal to captivity or euthanize it. If a gray wolf is taken into captivity for care or is euthanized, it must be reported to the Service within 24 hours or as soon as reasonably appropriate.

(9) *Review and evaluation of the success or failure of the NEP.* Radio transmitters, remote cameras, surveys of roads and trails to document wolf sign, and other monitoring techniques will be used to document wolf reproductive success, abundance, and distribution in Colorado post-release.

(i) To evaluate progress toward achieving State downlisting and delisting criteria, the State of Colorado will summarize monitoring information in an annual report. The report, due by June 30 of each year, will describe wolf conservation and management activities that occurred in Colorado for as long as the gray wolf is federally listed during any portion of a calendar or biological year. The annual report may include, but not be limited to: post-release wolf movements and behavior; wolf minimum counts or abundance estimates; reproductive success and recruitment; territory use and distribution; cause-specific wolf mortalities; and a summary of wolf conflicts and associated management activities to minimize wolf conflict risk.

(ii) To assess the reintroduction program, the Service will evaluate Colorado's wolf reintroduction and management program in a summary report each year that wolf reintroductions occur in the State and for a minimum of 5 years after reintroductions are complete. If the Service determines that modifications to reintroduction protocols and wolf monitoring and management activities are needed, the Service will coordinate closely with the State to ensure progress toward achieving their State recovery goals while concurrently minimizing wolf-related conflicts in Colorado.

(10) *Memorandum of Agreement (MOA).* The State of Colorado or any Tribe within the State, subject to the terms of this rule, may request an MOA from the Service to take over lead management responsibility and authority to implement this rule by managing the nonessential experimental gray wolves in the State or on a Tribal reservation, and implement all parts of

their State or Tribal plan that are consistent with this rule, provided that the State or Tribe has a wolf management plan approved by the Service.

(i) The State or Tribal request for wolf management under an MOA must demonstrate:

(A) That authority and management capability reside in the State or Tribe to conserve the gray wolf throughout the geographical range of the experimental population within the State of Colorado or within the Tribal reservation;

(B) That the State or Tribe has an acceptable conservation program for the gray wolf, throughout the NEP area within the State or Tribal reservation, including the requisite authority and capacity to carry out that conservation program;

(C) Exactly what parts of the State or Tribal plan the State or Tribe intends to implement within the framework of this rule; and

(D) That the State or Tribal management progress will be reported to the Service on at least an annual basis so the Service can determine if State or Tribal management was conducted in full compliance with this rule.

(ii) The Service will approve such a request upon a finding that the applicable criteria are met and that approval is not likely to jeopardize the continued existence of the gray wolf.

(iii) If the Service approves the request, the Service will enter into an MOA with the State or Tribe.

(iv) An MOA for State or Tribal management as provided in this rule may allow the State of Colorado or any Tribe within the State to become designated agents and lead management of the nonessential experimental gray wolf population within the borders of their jurisdictions in accordance with the State's or Tribe's wolf management plan, except that:

(A) The MOA may not provide for any form of management inconsistent with the protection provided to the species under this rule, without further opportunity for appropriate public comment and review and amendment of this rule.

(B) The MOA cannot vest the State of Colorado or any Tribe within the State with any authority over matters concerning section 4 of the Act (determining whether a species warrants listing).

(C) In the absence of a Tribal wolf management plan or cooperative agreement, the MOA cannot vest the State of Colorado with the authority to issue written authorizations for wolf take on reservations. The Service will retain the authority to issue these written authorizations until a Tribal wolf management plan is developed.

(D) The MOA for State or Tribal wolf management must provide for joint law enforcement responsibilities to ensure that the Service also has the authority to enforce the State or Tribal management program prohibitions on take.

(E) The MOA may not authorize wolf take beyond that stated in the rule but may be more restrictive.

(v) The authority for the MOA will be the Act, the Fish and Wildlife Act of 1956 (16 U.S.C. 742a–742j), and the Fish and Wildlife Coordination Act (16 U.S.C. 661–667e), and any applicable treaty.

(vi) In order for the MOA to remain in effect, the Service must find, on an annual basis, that the management under the MOA is not jeopardizing the continued existence of the gray wolf in the NEP. The Service or State or Tribe may terminate the MOA upon 90 days' notice if:

(A) Management under the MOA is likely to jeopardize the continued existence of the gray wolf in the NEP;

(B) The State or Tribe has failed materially to comply with this rule, the MOA, or any relevant provision of the State or Tribal wolf management plan;

(C) The Service determines that biological circumstances within the range of the gray wolf indicate that delisting the species is warranted; or

(D) The States or Tribes determine that they no longer want the wolf management authority vested in them by the Service in the MOA.

* * * * *

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2023–24514 Filed 11–7–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 231030–0254]

RIN 0648–BM33

Atlantic Highly Migratory Species; 2024 Atlantic Shark Commercial Fishing Year

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

ACTION: Final rule.

SUMMARY: This final rule adjusts the quotas and retention limits and establishes the opening date for the 2024 fishing year for the Atlantic shark commercial fisheries. NMFS also changes the management measures for the 2024 and future fishing years to automatically open the commercial fishing year on January 1 of each year under the base quotas and default retention limits, and increases the default commercial retention limit for the large coastal shark (LCS) fisheries. Quotas are adjusted as required or allowable based on any underharvests from the previous fishing years. The final measures could affect fishing opportunities for commercial shark fishermen in the northwestern Atlantic Ocean, Gulf of Mexico, and Caribbean Sea.

DATES: This final rule is effective on January 1, 2024. The 2024 Atlantic shark commercial fishing year opens on January 1, 2024 for all species and regions.

ADDRESSES: Electronic copies of this final rule and supporting documents (including the annual Atlantic Highly Migratory Species (HMS) Stock Assessment and Fishery Evaluation Report) are available from the Atlantic HMS Management Division website at *https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species* or by contacting Ann Williamson at *ann.williamson@noaa.gov* or 301–427–8503.

FOR FURTHER INFORMATION CONTACT: Ann Williamson (*ann.williamson@noaa.gov*), Guy DuBeck (*guy.dubeck@noaa.gov*), or Karyl Brewster-Geisz (*karyl.brewster-geisz@noaa.gov*) at 301–427–8503.

SUPPLEMENTARY INFORMATION:

Background

Atlantic shark fisheries are managed under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (2006 Consolidated HMS FMP) and its amendments are implemented by regulations at 50 CFR part 635. The shark commercial retention limits, quotas, and closure requirements can be found in §§ 635.24(a), 635.27(b), and 635.28(b), respectively.

For the Atlantic shark commercial fisheries, the 2006 Consolidated HMS FMP and its amendments established default commercial shark retention limits, commercial quotas for species

and management groups, and adjustment procedures for underharvests and overharvests. Regulations also include provisions allowing flexible opening dates for the fishing year (§ 635.27(b)(3)) and inseason adjustments to shark trip limits (§ 635.24(a)(8)), which provide management flexibility in furtherance of equitable fishing opportunities, to the extent practicable, for commercial shark fishermen in all regions and areas. In addition, § 635.28(b)(4) lists species and management groups with quotas that are linked. If quotas are linked, when the specified quota threshold for one management group or species is reached and that management group or species is closed, the linked management group or species closes at the same time (§ 635.28(b)(3)). Lastly, pursuant to § 635.27(b)(2), any annual or inseason adjustments to the base annual commercial overall, regional, or sub-regional quotas will be published in the **Federal Register**.

Background information about the need to adjust the quotas and retention limits and establish the opening date for the 2024 and future fishing years for the Atlantic commercial shark fisheries was provided in the proposed rule (88 FR 50822, August 2, 2023) and is not repeated here. The comment period for the proposed rule closed on September 1, 2023. NMFS received two written comments. Summaries of the comments received, and our responses to those comments, are in the Response to Comments section. Similar comments are combined, where appropriate. After reviewing and considering all the public comments received on the proposed rule, NMFS is finalizing the rule as proposed.

Final Opening Date and Retention Limit Measures

After considering the ''Opening Commercial Fishing Season Criteria'' listed at § 635.27(b)(3), and ''Inseason Trip Limit Adjustment Criteria'' listed at § 635.24(a)(8), NMFS is opening the 2024 Atlantic commercial shark fishing season for all shark management groups in the northwestern Atlantic Ocean, including the Gulf of Mexico and Caribbean Sea, on January 1, 2024. NMFS is also starting the 2024 commercial shark fishing season with the commercial retention limit of 55 LCS other than sandbar sharks per vessel per trip in both the eastern and western Gulf of Mexico sub-regions as well as in the Atlantic region (Table 1). As needed, NMFS may adjust the retention limit throughout the year to ensure equitable fishing opportunities throughout the region and ensure the quota is not exceeded (see the criteria at § 635.24(a)(8)).

Additionally, NMFS revises the regulations for both the start date for all Atlantic shark fisheries and the default retention limit for Shark Directed permit holders in the LCS fisheries. Specifically regarding the start date, NMFS revises the regulations at § 635.27(b) to have the fishery automatically open on January 1 each year under base quotas and default retention limits. NMFS maintains the flexibility to prevent a regional or sub-regional shark management group from automatically opening on January 1 if the respective quota is overharvested or there are indications that opening on January 1 would result in the quota being overharvested. A change in opening date for a regional or sub-regional shark management group could occur during the respective fishing year or prior to January 1 for the following fishing year. Before changing the opening date from January 1, NMFS would consider the seven ''Opening Commercial Fishing Season Criteria'' listed at § 635.27(b)(3). Each year, during the fishing year, NMFS would follow the quota adjustment process specified in § 635.27(b)(2) and publish in the **Federal Register** an adjustment for any quota over- or underharvests based on landings reported from the previous fishing year.

Regarding the default retention limit, NMFS revises the regulations at § 635.24(a) to change the default commercial retention limit to 55 LCS other than sandbar sharks per vessel per trip for Shark Directed limited access permit holders. NMFS does not change the existing regulations that allow for changes to the retention limit during the fishing year. Specifically, NMFS could continue to adjust the retention limit from 0 to 55 LCS other than sandbar sharks per vessel per trip if the respective LCS management group is open under §§ 635.27 and 635.28, and after considering the seven ''Inseason Trip Limit Adjustment'' criteria at § 635.24(a)(8).

Consistent with existing regulations, all of the regional or sub-regional commercial fisheries for shark management groups would remain open until December 31 each year, or until NMFS determines that the landings for any shark management group are projected to reach 80 percent of the quota given the realized catch rates and are projected to reach 100 percent of the quota before the end of the fishing season, or until a quota-linked species or management group is closed. For the regional or sub-regional Gulf of Mexico blacktip shark management group(s), regulations at § 635.28(b)(5)(i) through (v) authorize NMFS to close the management group(s) before landings have reached, or are projected to reach, 80 percent of the quota after considering the criteria and other relevant factors. NMFS manages each Atlantic shark management group by using a specific commercial annual catch limit, with some linkages among shark management groups whose species are often caught together. The linked and non-linked quotas are shown in Table 1.

If NMFS determines that shark species and/or management group must be closed, then NMFS will publish in the **Federal Register** a notice of closure for that shark species, management group, region, and/or sub-region. The closure will be effective no fewer than 4 days from the date of filing for public inspection with the Office of the Federal Register. In that event, from the effective date and time of the closure until the start of the following fishing year or until NMFS announces that the season is reopened and additional quota is available (via publication of another notice in the **Federal Register**), the fisheries for the shark species and/or management groups will be closed.

TABLE 1—QUOTA LINKAGES AND COMMERCIAL RETENTION LIMIT BY REGIONAL OR SUB-REGIONAL SHARK MANAGEMENT GROUP

Region or sub-region	Management group	Quota linkages [1]	Commercial retention limits for directed shark limited access permit holders [2]
Western Gulf of Mexico	Blacktip Sharks	Not Linked	55 LCS other than sandbar sharks per vessel per trip.
	Aggregated LCS	Linked.	
	Hammerhead Sharks.		
Eastern Gulf of Mexico	Blacktip Sharks	Not Linked	55 LCS other than sandbar sharks per vessel per trip.
	Aggregated LCS	Linked.	

TABLE 1—QUOTA LINKAGES AND COMMERCIAL RETENTION LIMIT BY REGIONAL OR SUB-REGIONAL SHARK MANAGEMENT GROUP—Continued

Region or sub-region	Management group	Quota linkages [1]	Commercial retention limits for directed shark limited access permit holders [2]
	Hammerhead Sharks.		
Gulf of Mexico	Non-Blacknose SCS	Not Linked	N/A.
	Smoothhound Sharks	Not Linked	N/A.
Atlantic	Aggregated LCS	Linked	55 LCS other than sandbar sharks per vessel per trip.
	Hammerhead Sharks.		
	Non-Blacknose SCS	Linked (South of 34° N lat. Only)	N/A.
	Blacknose Sharks (South of 34° N lat. Only)		8 blacknose sharks per vessel per trip [3].
	Smoothhound Sharks	Not Linked	N/A.
No Regional Quotas	Non-Sandbar LCS Research	Linked [4]	N/A.
	Sandbar Shark Research.		
	Blue Sharks	Not Linked	N/A.
	Porbeagle Sharks.		
	Pelagic Sharks Other Than Porbeagle or Blue.		

[1] Section 635.28(b)(4) lists species and management groups with quotas that are linked. If quotas are linked, when the specified quota threshold for one management group or species is reached and that management group or species is closed, the linked management group or species closes at the same time (§ 635.28(b)(3)).
[2] Inseason adjustments are possible.
[3] Applies to Shark Directed and Shark Incidental permit holders.
[4] Shark research permits ''terms and conditions'' state that when the individual sandbar or research LCS quotas authorized by the permit are landed, all fishing trips under the permit must stop.

Final 2024 Commercial Shark Quotas

In this final rule, NMFS adjusts the quota levels for the various shark stocks and management groups for the 2024 Atlantic shark commercial fishing year (*i.e.,* January 1 through December 31, 2024) based on underharvests that occurred during the 2023 fishing year, consistent with existing regulations at § 635.27(b). Overharvests and underharvests are accounted for in the same region, sub-region, or fishery in which they occurred the following year, except that large overharvests may be spread over a maximum of 5 fishing years. Unharvested quota may be added to the quota for the next fishing year, but only for shark management groups that have shark stocks that are declared not overfished and not experiencing overfishing. No more than 50 percent of a base annual quota may be carried over from a previous fishing year.

Based on 2023 harvests through September 18, 2023, and after considering catch rates and landings from previous years, NMFS adjusts the 2024 quotas for certain management groups as shown in Table 2. NMFS anticipates that dealer reports received after September 18, 2023 will be used to adjust 2025 quotas, as appropriate, noting that, in some circumstances, NMFS re-adjusts quotas during the subject year. A description of the calculations for each stock and management group is provided in the proposed rule and is not repeated here.

TABLE 2—2024 QUOTAS FOR THE ATLANTIC SHARK MANAGEMENT GROUPS

Region or sub-region	Management group (A)	2023 Annual quota (B)	Preliminary 2023 landings [1] (C)	Adjustments [2] (D)	2024 Base annual quota (D+C)	2024 Final annual quota
Western Gulf of Mexico	Blacktip Sharks	347.2 mt (765,392 lb).	235.5 mt (519,232 lb).	115.7 mt (225,131 lb).	231.5 mt (510,261 lb).	347.2 mt (765,392 lb).
	Aggregate Large Coastal Sharks [3].	72.0 mt (158,724 lb)	77.8 mt (171,540 lb)		72.0 mt (158,724 lb)	72.0 mt (158,724 lb).
	Hammerhead Sharks	11.9 mt (26,301 lb) ..	<3.0 mt (<6,612 lb) ..		11.9 mt (26,301 lb) ..	11.9 mt (26,301 lb).
Eastern Gulf of Mexico	Blacktip Sharks	37.7 mt (83,158 lb) ..	3.8 mt (8,345 lb)	12.6 mt (27,719 lb) ..	25.1 mt (55,439 lb) ..	37.7 mt (83,158 lb).
	Aggregate Large Coastal Sharks [3].	85.5 mt (188,593 lb)	5.6 mt (12,260 lb)		85.5 mt (188,593 lb)	85.5 mt (188,593 lb).
	Hammerhead Sharks	13.4 mt (29,421 lb) ..	<1.0 mt (<2,204 lb) ..		13.4 mt (29,421 lb) ..	13.4 mt (29,421 lb).
Gulf of Mexico	Non-Blacknose Small Coastal Sharks.	112.6 mt (428,215 lb).	32.7 mt (71,987 lb) ..		112.6 mt (428,215 lb).	112.6 mt (428,215 lb).
	Smoothhound Sharks.	504.6 mt (1,112,441 lb).	<1.0 mt (<2,204 lb) ..	168.2 mt (370,814 lb).	336.4 mt (741,627 lb).	504.6 mt (1,112,441 lb).
Atlantic	Aggregate Large Coastal Sharks.	168.9 mt (372,552 lb).	78.5 mt (172,983 lb)		168.9 mt (372,552 lb).	168.9 mt (372,552 lb).
	Hammerhead Sharks	27.1 mt (59,736 lb) ..	19.9 mt (43,800 lb) ..		27.1 mt (59,736 lb) ..	27.1 mt (59,736 lb).
	Non-Blacknose Small Coastal Sharks.	264.1 mt (582,333 lb).	52.5 mt (115,820 lb)		264.1 mt (582,333 lb).	264.1 mt (582,333 lb).
	Blacknose Sharks (South of 34° N lat. Only).	17.2 mt (3,921 lb)	4.7 mt (10,363 lb)		17.2 mt (3,921 lb)	17.2 mt (3,921 lb).
	Smoothhound Sharks.	1,802.6 mt (3,973,902 lb).	290.6 mt (640,557 lb).	600.9 mt (1,324,634 lb).	1,201.7 mt (2,649,268 lb).	1,802.6 mt (3,973,902 lb).
No Regional Quotas	Non-Sandbar LCS Research.	50.0 mt (110,230 lb)	<2.0 mt (<4,408 lb) ..		50.0 mt (110,230 lb)	50.0 mt (110,230 lb).
	Sandbar Shark Research.	90.7 mt (199,943 lb)	<22.0 mt (<48,500 lb).		90.7 mt (199,943 lb)	90.7 mt (199,943 lb).
	Blue Sharks	273.0 mt (601,856 lb).	<2.0 mt (<4,408 lb) ..		273.0 mt (601,856 lb).	273.0 mt (601,856 lb).
	Porbeagle Sharks	1.7 mt (3,748 lb)	<1.0 mt (<2,204 lb) ..		1.7 mt (3,748 lb)	1.7 mt (3,748 lb).

TABLE 2—2024 QUOTAS FOR THE ATLANTIC SHARK MANAGEMENT GROUPS—Continued

Region or sub-region	Management group	2023 Annual quota	Preliminary 2023 landings [1]	Adjustments [2]	2024 Base annual quota	2024 Final annual quota
	(A)	(B)	(C)	(D)	(D+C)	
	Pelagic Sharks Other Than Porbeagle or Blue.	488.0 mt (1,075,856 lb).	15.5 mt (34,131 lb) ..	.....	488.0 mt (1,075,856 lb).	488.0 mt (1,075,856 lb).

[1] Landings are from January 1, 2023 through September 18, 2023 and are subject to change.
[2] Underharvest adjustments can only be applied to stocks or management groups that are declared not overfished and have no overfishing occurring. The underharvest adjustments cannot exceed 50 percent of the base quota.
[3] NMFS transferred 40.0 mt dw of the aggregate LCS quota from the Gulf of Mexico eastern sub-region to the western sub-region as of March 21, 2023 (88 FR 17742, March 24, 2023).

Response to Comments

Written comments can be found at *http://www.regulations.gov/* by searching ''NOAA–NMFS–2023–0018.'' Below, NMFS summarizes and responds to the two written comments received on the proposed rule during the comment period. Similar comments are combined, where appropriate.

Comment: NMFS received two comments that requested a prohibition on all shark fishing, expressing concern over the stock status of Atlantic shark species. Specifically, one of the comments stated that commercial harvest of sharks is not sustainable, and commercial shark fishing should be prohibited until shark populations have recovered.

Response: NMFS disagrees with the statement that commercial harvest of sharks is not sustainable. Under the Magnuson-Stevens Act, NMFS is required to foster the long-term biological and economic sustainability of fisheries, including the shark fishery. The majority of sharks harvested in the United States are from stocks with above-target population levels. For shark stocks that are overfished, NMFS has established rebuilding plans based on the best scientific information available. Most of these rebuilding plans include some level of commercial harvest. For those shark stocks that are experiencing overfishing, NMFS has implemented management measures, which may include strict catch limits, to end overfishing. The primary objective of this final rule is to adjust the base quotas and retention limits as necessary and consistent with existing regulations at §§ 635.24(a) and 635.27(b), and to change the default opening date for all Atlantic shark fisheries and the default retention limit measures for LCS fisheries for future fishing years. Prohibiting all shark fishing is contrary to that objective and to the requirements of the Magnuson-Stevens Act.

Classification

The NMFS Assistant Administrator has determined that this final rule is consistent with the 2006 Consolidated HMS FMP and its amendments, the Magnuson-Stevens Act, and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a final regulatory flexibility analysis was not required and none was prepared.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 635

Fisheries, Fishing, Fishing vessels, Foreign relations, Imports, Penalties, Reporting and recordkeeping requirements, Statistics, Treaties.

Dated: October 31, 2023.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 635 as follows:

PART 635—ATLANTIC HIGHLY MIGRATORY SPECIES

■ 1. The authority citation for part 635 continues to read as follows:

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

■ 2. In § 635.24, revise paragraph (a)(2) to read as follows:

§ 635.24 Commercial retention limits for sharks, swordfish, and BAYS tunas.

* * * * *

(a) * * *

(2) The commercial retention limit for LCS other than sandbar sharks for a person who owns or operates a vessel that has been issued a directed LAP for sharks and does not have a valid shark research permit, or a person who owns or operates a vessel that has been issued a directed LAP for sharks and that has been issued a shark research permit but does not have a NMFS-approved observer on board, may range between 0 and 55 LCS other than sandbar sharks per vessel per trip if the respective LCS management group(s) is open per §§ 635.27 and 635.28. Such persons may not retain, possess, or land sandbar sharks. At the start of each fishing year, the default commercial retention limit is 55 LCS other than sandbar sharks per vessel per trip unless NMFS determines otherwise and files with the Office of the Federal Register for publication notification of an inseason adjustment. During the fishing year, NMFS may adjust the retention limit per the inseason trip limit adjustment criteria listed in paragraph (a)(8) of this section.

* * * * *

■ 3. In § 635.27, revise paragraphs (b)(2) introductory text and (b)(3) introductory text to read as follows:

§ 635.27 Quotas.

* * * * *

(b) * * *

(2) *Annual and inseason adjustments of commercial quotas.* NMFS will publish in the **Federal Register** any annual or inseason adjustments to the base annual commercial overall, regional, or sub-regional quotas. Unless the opening date of a commercial shark fishery is adjusted under paragraph (b)(3) of this section, on January 1 of each year, base quotas, as established in paragraph (b)(1) of this section, will be available, and any adjustments will be published in the **Federal Register**. Within a fishing year or at the start of a fishing year, NMFS may transfer quotas between regions and sub-regions of the same species or management group, as appropriate, based on the

criteria in paragraph (b)(2)(iii) of this section.

* * * * *

(3) *Opening commercial fishing season.* Unless adjusted under this paragraph (b)(3), the commercial shark fisheries will open on January 1 of each year under base quotas, as established in paragraph (b)(1) of this section. If NMFS determines a commercial shark fishery or a part of a commercial shark fishery should open on a date other than January 1, NMFS will file with the Office of the Federal Register for publication notification of the opening date(s) of the relevant overall, regional, or sub-regional shark fishery(ies) for the relevant species or management group(s). Before making any decisions, NMFS would consider the following criteria and other relevant factors in establishing the opening date(s):

* * * * *

■ 4. In § 635.28, revise paragraphs (b)(2) and (3) to read as follows:

§ 635.28 Fishery closures.

* * * * *

(b) * * *

(2) *Non-linked quotas.* If the overall, regional, and/or sub-regional quota of a species or management group is not linked to another species or management group and that overall, regional, and/or sub-regional quota is available, then that overall, regional, and/or sub-regional commercial fishery for the shark species or management group will open as specified in § 635.27(b). When NMFS calculates that the overall, regional, and/or sub-regional landings for a shark species and/or management group, as specified in § 635.27(b)(1), has reached or is projected to reach 80 percent of the applicable available overall, regional, and/or sub-regional quota as specified in § 635.27(b)(1) and is projected to reach 100 percent of the relevant quota by the end of the fishing season, NMFS will file for publication with the Office of the Federal Register a closure action, as applicable, for that shark species and/or shark management group that will be effective no fewer than 4 days from date of filing. From the effective date and time of the closure until the start of the following fishing year or until NMFS announces, via publication in the **Federal Register**, that additional overall, regional, and/or sub-regional quota is available and the season is reopened, the overall, regional, and/or sub-regional fisheries for that shark species or management group are closed.

(3) *Linked quotas.* As specified in paragraph (b)(4) of this section, the overall, regional, and/or sub-regional quotas of some shark species and/or management groups are linked to the overall, regional, and/or sub-regional quotas of other shark species and/or management groups. For each pair of linked species and/or management groups, if the overall, regional, and/or sub-regional quota specified in § 635.27(b)(1) is available for both of the linked species and/or management groups, then the overall, regional, and/or sub-regional commercial fishery for both of the linked species and/or management groups will open as specified in § 635.27(b)(1). When NMFS calculates that the overall, regional, and/or sub-regional landings for any species and/or management group of a linked group have reached or are projected to reach 80 percent of the applicable available overall, regional, and/or sub-regional quota as specified in § 635.27(b)(1) and are projected to reach 100 percent of the relevant quota before the end of the fishing season, NMFS will file for publication with the Office of the Federal Register a closure action for all of the species and/or management groups in that linked group that will be effective no fewer than 4 days from date of filing. From the effective date and time of the closure until the start of the following fishing year or until NMFS announces, via publication in the **Federal Register**, that additional overall, regional, and/or sub-regional quota is available and the season is reopened, the overall, regional, and/or sub-regional fishery for all species and/or management groups in that linked group is closed.

* * * * *

[FR Doc. 2023–24307 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 88, No. 215
Wednesday, November 8, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2139; Project Identifier MCAI–2023–00435–T]

RIN 2120–AA64

Airworthiness Directives; 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 Bombardier, Inc., Model BD–700–2A12 airplanes. This proposed AD was prompted by reports from the supplier that some overheat detection sensing elements of the bleed air leak detection system were manufactured with insufficient salt fill, which can result in an inability to detect hot bleed air leaks. This proposed AD would require maintenance records verification, and if an affected part is installed, would prohibit the use of certain Master Minimum Equipment List (MMEL) items under certain conditions by requiring revising the operator's existing MEL. This proposed AD would also require testing the overheat detection sensing elements, marking each serviceable sensing element with a witness mark, and replacing each nonserviceable part with a serviceable part. This proposed AD would also prohibit the installation of affected parts under certain conditions. 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 December 26, 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–2023–2139; 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 Bombardier service information identified in this NPRM, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email: *ac.yul@aero.bombardier.com;* website: *bombardier.com.*
- For Liebherr-Aerospace Toulouse SAS service information identified in this NPRM, contact Liebherr-Aerospace Toulouse SAS, 408, Avenue des Etats-Unis—B.P.52010, 31016 Toulouse Cedex, France; telephone +33 (0)5.61.35.28.28; fax +33 (0)5.61.35.29.29; email: *techpub.toulouse@liebherr.com;* website: *www.liebherr.aero.*
- 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: Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 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–2023–2139; Project Identifier MCAI–2023–00435–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 the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 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–2023–18, dated March 9, 2023 (Transport Canada AD CF–2023–18) (also referred to after this as the MCAI), to correct an unsafe condition on certain Bombardier,

Inc., Model BD–700–2A12 airplanes. The MCAI states that Bombardier received reports from the supplier of the overheat detection sensing elements of a manufacturing quality escape. Some of the sensing elements of the bleed air leak detection system were manufactured with insufficient salt fill. This condition can result in an inability to detect hot bleed air leaks, which can cause damage to surrounding structures and systems and prevent continued safe flight and landing.

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–2023–2139.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Liebherr Service Bulletin CFD–F1958–26–01, dated May 6, 2022, which specifies part numbers for affected sensing elements.

The FAA reviewed Bombardier Service Bulletin 700–36–7503, dated December 23, 2022, which specifies procedures for testing each leak detection loop (LDL) sensing element installed on the airplane, marking each serviceable sensing element with a witness mark, and replacing each nonserviceable part with a serviceable part.

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.

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 and service information described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require maintenance records verification. If an affected part is installed, this proposed AD would prohibit the use of certain MMEL items unless specific dispatch instructions are followed by revising the operator's existing MEL and accomplishing the actions specified in the service information already described. For certain airplanes, this proposed AD would also require testing each LDL sensing element installed on the airplane, marking each serviceable sensing element with a witness mark, and replacing each nonserviceable part with a serviceable part. This proposed AD would also prohibit the installation of affected parts under certain conditions.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 19 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
Up to 214 work-hours × $85 per hour = Up to $18,190.	$0	Up to $18,190	Up to $345,610.

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions specified in this proposed AD. The FAA estimates it would take up to 1.5 hours to replace a sensing element.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this proposed 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

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:

Bombardier, Inc.: Docket No. FAA–2023–2139; Project Identifier MCAI–2023–00435–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 26, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–2A12 airplanes, certificated in any category, having serial numbers 70005 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code: 36, Pneumatic.

(e) Unsafe Condition

This AD was prompted by reports that some overheat detection sensing elements of the bleed air leak detection system were manufactured with insufficient salt fill. The FAA is issuing this AD to address non-conforming sensing elements of the bleed air leak detection system. The unsafe condition, if not addressed, could result in an inability to detect hot bleed air leaks and consequent damage to surrounding structures and systems, which could prevent continued safe flight and landing.

(f) Compliance

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

(g) Definitions

For the purpose of this AD, the definitions specified in paragraphs (g)(1) and (2) of this AD apply.

(1) An affected part is a sensing element marked with a date code before A2105 and having an LTS/Kidde part number specified in Liebherr Service Bulletin CFD–F1958–26–01, dated May 6, 2022, unless that sensing element meets the criteria specified in paragraph (g)(1)(i) or (ii) of this AD.

(i) The sensing element has been tested as specified in Section 3 of the Accomplishment Instructions of Kidde Aerospace and Defense Service Bulletin CFD–26–1, Revision 6, dated February 28, 2022, or earlier revisions, and has been found to be serviceable; and the sensing element has been marked on one face of its connector hex nut and packaged as specified in Section 3.C. of the Accomplishment Instructions of Kidde Aerospace and Defense Service Bulletin CFD–26–1, Revision 6, dated February 28, 2022, or earlier revisions.

(ii) The sensing element has been tested and found to be serviceable as specified in paragraph (j) of this AD; and the sensing element has been marked on one face of one connector hex nut with one green mark, as specified in Figure 33 of Bombardier Service Bulletin 700–36–7503, dated December 23, 2022, as applicable (the figure is representative for all sensing elements).

(2) A serviceable part is a sensing element that is not an affected part.

(h) Maintenance Records Verification

For airplane serial numbers 70097 and subsequent whose airplane date of manufacture, as identified on the identification plate of the airplane, is on or before the effective date of this AD: Within 60 days after the effective date of this AD, examine the airplane maintenance records to verify whether any affected part has been installed since the airplane date of manufacture, as identified on the identification plate of the airplane.

(1) If the maintenance records confirms that an affected part has been installed, or if it cannot be confirmed that an affected part has not been installed, paragraphs (i) and (j) of this AD must be complied with within the compliance time specified in paragraphs (i) and (j) of this AD.

(2) If the maintenance records confirm that no affected parts have been installed since airplane date of manufacture, then paragraphs (i) and (j) of this AD are not applicable.

(i) Minimum Equipment List (MEL) Revision

For all airplanes: Within 90 days after the effective date of this AD, revise the operator's existing MEL by incorporating the information specified in figures 1 through 7 to paragraph (i) of this AD, as applicable. This may be done by inserting a copy of this information into the operator's existing MEL.

Figure 1 to Paragraph (i)—MMEL Item 21–0425

BILLING CODE 4910–13–P

MMEL Item 21-0425

Crew Alerting System (CAS) Message	1. Repair Category	2. Dispatch Consideration
21 AIR COND / PRESS – TRIM LOOP ONE ELEMENT INOP	C	(O) May be displayed provided none of the following messages are displayed: – 21 AIR COND / PRESS – IASC 1B INOP – 21 AIR COND / PRESS – IASC 2B INOP – 21 AIR COND / PRESS – IASC 1B FAULT – 21 AIR COND / PRESS – IASC 2B FAULT

1. OPERATIONS (O)

Before each flight:

(1) Make sure that the airplane is not powered on and that engines and APU are OFF.

a. Connect electrical power to the airplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

i. Connect external AC power, OR

ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the MAIN BATT and APU BATT switches to ON.

2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.

3. On the APU control panel, turn the APU switch to START.

b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

c. After 6 minutes, check for the 21 AIR COND / PRESS – TRIM LOOP ONE ELEMENT
INOP info message as follows:

i. If the 21 AIR COND / PRESS – TRIM LOOP ONE ELEMENT INOP info message shows – DISPATCH IS PERMITTED.

Note: The INFO message confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

ii. If the 21 AIR COND / PRESS – TRIM LOOP ONE ELEMENT INOP info message does not show – DISPATCH IS NOT PERMITTED.

Note: No INFO message confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

d. If required, remove external AC power from the airplane.

e. If required, set APU BLEED to AUTO.

(2) On the INFO synoptic page, make sure that the messages that follow do not show:

Note: Confirm the airplane has electrical power to activate the synoptic page.

– 21 AIR COND / PRESS – IASC 1B INOP info

– 21 AIR COND / PRESS – IASC 2B INOP info

– 21 AIR COND / PRESS – IASC 1B FAULT info

– 21 AIR COND / PRESS – IASC 2B FAULT info

Figure 2 to Paragraph (i)—MMEL Item 30–0055

MMEL Item 30-0055

CAS Message	1. Repair Category	2. Dispatch Consideration
30 ICE PROT – L WING LOOP ONE ELEMENT INOP	C	(O) May be displayed provided none of the following messages are displayed: – 21 AIR COND / PRESS – IASC 1B INOP – 21 AIR COND / PRESS – IASC 2B INOP – 21 AIR COND / PRESS – IASC 1B FAULT – 21 AIR COND / PRESS – IASC 2B FAULT

1. OPERATIONS (O)

Before each flight:

(1) Make sure that the airplane is not powered on and that engines and APU are OFF.

a. Connect electrical power to the airplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

i. Connect external AC power, OR

ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the MAIN BATT and APU BATT switches to ON.

2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.

3. On the APU control panel, turn the APU switch to START.

b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

c. After 6 minutes, check for the 30 ICE PROT – L WING LOOP ONE ELEMENT INOP info message as follows:

i. If the 30 ICE PROT – L WING LOOP ONE ELEMENT INOP info message shows
– DISPATCH IS PERMITTED.

Note: The INFO message confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

ii. If the 30 ICE PROT – L WING LOOP ONE ELEMENT INOP info message does
not show – DISPATCH IS NOT PERMITTED.

Note: No INFO message confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

d. If required, remove external AC power from the airplane.

e. If required, set APU BLEED to AUTO.

(2) On the INFO synoptic page, make sure that the messages that follow do not show:

Note: Confirm the airplane has electrical power to activate the synoptic page.

– 21 AIR COND / PRESS – IASC 1B INOP info

– 21 AIR COND / PRESS – IASC 2B INOP info

– 21 AIR COND / PRESS – IASC 1B FAULT info

– 21 AIR COND / PRESS – IASC 2B FAULT info

Figure 3 to Paragraph (i)—MMEL Item 30–0060

MMEL Item 30-0060

CAS Message	1. Repair Category	2. Dispatch Consideration
30 ICE PROT – L WIPS LOOP ONE ELEMENT INOP	C	(O) May be displayed provided none of the following messages are displayed: – 21 AIR COND / PRESS – IASC 1B INOP – 21 AIR COND / PRESS – IASC 2B INOP – 21 AIR COND / PRESS – IASC 1B FAULT – 21 AIR COND / PRESS – IASC 2B FAULT

1. OPERATIONS (O)

Before each flight:

(1) Make sure that the airplane is not powered on and that engines and APU are OFF.

a. Connect electrical power to the airplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

i. Connect external AC power, OR

ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the MAIN BATT and APU BATT switches to ON.

2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.

3. On the APU control panel, turn the APU switch to START.

b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

c. After 6 minutes, check for the 30 ICE PROT – L WIPS LOOP ONE ELEMENT INOP info message as follows:

i. If the 30 ICE PROT – L WIPS LOOP ONE ELEMENT INOP info message shows
– DISPATCH IS PERMITTED.

Note: The INFO message confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

ii. If the 30 ICE PROT – L WIPS LOOP ONE ELEMENT INOP info message does
not show – DISPATCH IS NOT PERMITTED.

Note: No INFO message confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

d. If required, remove external AC power from the airplane.

e. If required, set APU BLEED to AUTO.

(2) On the INFO synoptic page, make sure that the messages that follow do not show:

Note: Confirm the airplane has electrical power to activate the synoptic page.

– 21 AIR COND / PRESS – IASC 1B INOP info

– 21 AIR COND / PRESS – IASC 2B INOP info

– 21 AIR COND / PRESS – IASC 1B FAULT info

– 21 AIR COND / PRESS – IASC 2B FAULT info

Figure 4 to Paragraph (i)—MMEL Item 30–0090

MMEL Item 30-0090

CAS Message	1. Repair Category	2. Dispatch Consideration
30 ICE PROT – R WING LOOP ONE ELEMENT INOP	C	(O) May be displayed provided none of the following messages are displayed: – 21 AIR COND / PRESS – IASC 1B INOP – 21 AIR COND / PRESS – IASC 2B INOP – 21 AIR COND / PRESS – IASC 1B FAULT – 21 AIR COND / PRESS – IASC 2B FAULT

1. OPERATIONS (O)

Before each flight:

(1) Make sure that the airplane is not powered on and that engines and APU are OFF.

a. Connect electrical power to the airplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

i. Connect external AC power, OR

ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the MAIN BATT and APU BATT switches to ON.

2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.

3. On the APU control panel, turn the APU switch to START.

b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

c. After 6 minutes, check for the 30 ICE PROT – R WING LOOP ONE ELEMENT INOP info message as follows:

i. If the 30 ICE PROT – R WING LOOP ONE ELEMENT INOP info message shows – DISPATCH IS PERMITTED.

Note: The INFO message confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

ii. If the 30 ICE PROT – R WING LOOP ONE ELEMENT INOP info message does
not show – DISPATCH IS NOT PERMITTED.

Note: No INFO message confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

d. If required, remove external AC power from the airplane.

e. If required, set APU BLEED to AUTO.

(2) On the INFO synoptic page, make sure that the messages that follow do not show:

Note: Confirm the airplane has electrical power to activate the synoptic page.

– 21 AIR COND / PRESS – IASC 1B INOP info

– 21 AIR COND / PRESS – IASC 2B INOP info

– 21 AIR COND / PRESS – IASC 1B FAULT info

– 21 AIR COND / PRESS – IASC 2B FAULT info

Figure 5 to Paragraph (i)—MMEL Item 30–0095

MMEL Item 30-0095

CAS Message	1. Repair Category	2. Dispatch Consideration
30 ICE PROT – R WIPS LOOP ONE ELEMENT INOP	C	(O) May be displayed provided none of the following messages are displayed: – 21 AIR COND / PRESS – IASC 1B INOP – 21 AIR COND / PRESS – IASC 2B INOP – 21 AIR COND / PRESS – IASC 1B FAULT – 21 AIR COND / PRESS – IASC 2B FAULT

1. OPERATIONS (O)

Before each flight:

(1) Make sure that the airplane is not powered on and that engines and APU are OFF.

a. Connect electrical power to the airplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

i. Connect external AC power, OR

ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the MAIN BATT and APU BATT switches to ON.

2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.

3. On the APU control panel, turn the APU switch to START.

b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

c. After 6 minutes, check for the 30 ICE PROT – R WIPS LOOP ONE ELEMENT INOP info message as follows:

i. If the 30 ICE PROT – R WIPS LOOP ONE ELEMENT INOP info message shows
– DISPATCH IS PERMITTED.

Note: The INFO message confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

ii. If the 30 ICE PROT – R WIPS LOOP ONE ELEMENT INOP info message does
not show – DISPATCH IS NOT PERMITTED.

Note: No INFO message confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

d. If required, remove external AC power from the airplane.

e. If required, set APU BLEED to AUTO.

(2) On the INFO synoptic page, make sure that the messages that follow do not show:

Note: Confirm the airplane has electrical power to activate the synoptic page.

– 21 AIR COND / PRESS – IASC 1B INOP info

– 21 AIR COND / PRESS – IASC 2B INOP info

– 21 AIR COND / PRESS – IASC 1B FAULT info

– 21 AIR COND / PRESS – IASC 2B FAULT info

Figure 6 to Paragraph (i)—MMEL Item 36–0050

MMEL Item 36-0050

CAS Message	1. Repair Category	2. Dispatch Consideration
36 BLEED – L BLEED LOOP ONE ELEMENT INOP	C	(O) May be displayed provided none of the following messages are displayed: – 21 AIR COND / PRESS – IASC 1B INOP – 21 AIR COND / PRESS – IASC 2B INOP – 21 AIR COND / PRESS – IASC 1B FAULT – 21 AIR COND / PRESS – IASC 2B FAULT

1. OPERATIONS (O)

Before each flight:

(1) Make sure that the airplane is not powered on and that engines and APU are OFF.

a. Connect electrical power to the airplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

i. Connect external AC power, OR

ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the MAIN BATT and APU BATT switches to ON.

2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.

3. On the APU control panel, turn the APU switch to START.

b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

c. After 6 minutes, check for the 36 BLEED – L BLEED LOOP ONE ELEMENT INOP info message as follows:

i. If the 36 BLEED – L BLEED LOOP ONE ELEMENT INOP info message shows – DISPATCH IS PERMITTED.

Note: The INFO message confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

ii. If the 36 BLEED – L BLEED LOOP ONE ELEMENT INOP info message does not
show – DISPATCH IS NOT PERMITTED.

Note: No INFO message confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

d. If required, remove external AC power from the airplane.

e. If required, set APU BLEED to AUTO.

(2) On the INFO synoptic page, make sure that the messages that follow do not show:

Note: Confirm the airplane has electrical power to activate the synoptic page.

– 21 AIR COND / PRESS – IASC 1B INOP info

– 21 AIR COND / PRESS – IASC 2B INOP info

– 21 AIR COND / PRESS – IASC 1B FAULT info

– 21 AIR COND / PRESS – IASC 2B FAULT info

Figure 7 to Paragraph (i)—MMEL Item 36–0105

MMEL Item 36-0105

CAS Message	1. Repair Category	2. Dispatch Consideration
36 BLEED – R BLEED LOOP ONE ELEMENT INOP	C	(O) May be displayed provided none of the following messages are displayed: – 21 AIR COND / PRESS – IASC 1B INOP – 21 AIR COND / PRESS – IASC 2B INOP – 21 AIR COND / PRESS – IASC 1B FAULT – 21 AIR COND / PRESS – IASC 2B FAULT

1. OPERATIONS (O)

Before each flight:

(1) Make sure that the airplane is not powered on and that engines and APU are OFF.

a. Connect electrical power to the airplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

i. Connect external AC power, OR

ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the MAIN BATT and APU BATT switches to ON.

2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.

3. On the APU control panel, turn the APU switch to START.

b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

c. After 6 minutes, check for the 36 BLEED – R BLEED LOOP ONE ELEMENT INOP info message as follows:

i. If the 36 BLEED – R BLEED LOOP ONE ELEMENT INOP info message shows – DISPATCH IS PERMITTED.

Note: The INFO message confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

ii. If the 36 BLEED – R BLEED LOOP ONE ELEMENT INOP info message does
not show – DISPATCH IS NOT PERMITTED.

Note: No INFO message confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

d. If required, remove external AC power from the airplane.

e. If required, set APU BLEED to AUTO.

(2) On the INFO synoptic page, make sure that the messages that follow do not show:

Note: Confirm the airplane has electrical power to activate the synoptic page.

– 21 AIR COND / PRESS – IASC 1B INOP info

– 21 AIR COND / PRESS – IASC 2B INOP info

– 21 AIR COND / PRESS – IASC 1B FAULT info

– 21 AIR COND / PRESS – IASC 2B FAULT info

BILLING CODE 4910–13–C

(j) Testing and Replacement of Affected Overheat Detection Sensing Elements

For airplane serial numbers 70005 and subsequent: Within 3,500 flight hours or 120 months, whichever occurs first, from the effective date of this AD, test the overheat detection sensing elements to determine if they are serviceable, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 700–36–7503, dated December 23, 2022.

(1) For each sensing element that is serviceable, before further flight, mark the sensing element with a witness mark in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 700–36–7503, dated December 23, 2022.

(2) For each sensing element that is not serviceable, before further flight, replace the sensing element with a serviceable part in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 700–36–7503, dated December 23, 2022.

(k) Parts Installation Prohibition

As of the effective date of this AD, no person may install, on any airplane, any affected part unless it is a serviceable part.

(l) No Reporting Requirement

Although Bombardier Service Bulletin 700–36–7503, dated December 23, 2022, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(m) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to ATTN: Program Manager, Continuing Operational Safety, at the address identified in paragraph (n)(2) of this AD or email to: *9-avs-nyaco-cos@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(n) Additional Information

(1) Refer to Transport Canada AD CF–2023–18, dated March 9, 2023, for related information. This Transport Canada AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2023–2139.

(2) For more information about this AD, contact Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

(o) 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) Bombardier Service Bulletin 700–36–7503, dated December 23, 2022.

(ii) Liebherr Service Bulletin CFD–F1958–26–01, dated May 6, 2022.

(3) For Bombardier service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email: *ac.yul@aero.bombardier.com;* website: *bombardier.com.*

(4) For Liebherr-Aerospace Toulouse SAS service information identified in this AD, contact Liebherr-Aerospace Toulouse SAS, 408, Avenue des Etats-Unis—B.P.52010, 31016 Toulouse Cedex, France; telephone +33 (0)5.61.35.28.28; fax +33 (0)5.61.35.29.29; email: *techpub.toulouse@liebherr.com;* website: *www.liebherr.aero.*

(5) 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.

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

Issued on October 26, 2023.

Caitlin Locke,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–24008 Filed 11–7–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2143; Project Identifier MCAI–2023–00088–A]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries GmbH Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–21–15, which applies to certain Diamond Aircraft Industries GmbH (DAI) Model DA 42, DA 42 NG, and DA 42 M–NG airplanes. AD 2022–21–15 requires replacing the rudder T-yoke

axle with an improved rudder T-yoke axle. Since the FAA issued AD 2022–21–15, the European Union Aviation Safety Agency (EASA) superseded its mandatory continuing airworthiness information (MCAI) to correct an unsafe condition on these products. This proposed AD would require, for certain airplanes, inspecting the rudder steering bracket edge distance and depending on the inspection results, inspecting the T-yoke bolt hole for wear and play, and corrective action if necessary. For certain airplanes this proposed AD would require replacing the rudder T-yoke bolt (axle) with a serviceable part, and applying torque seal marks on the rudder T-yoke bolt head, and self-locking nut. For all airplanes this proposed AD would require repetitively inspecting the torque seal marks on the rudder T-yoke bolt head for proper alignment and the self-locking nut for proper installation and corrective action if necessary. This proposed AD would also prohibit the installation of affected parts. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by December 26, 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–2023–2143; 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 MCAI, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this NPRM, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A–2700 Wiener Neustadt, Austria; phone: +43 2622 26700; email: *airworthiness-austria@diamondaircraft.com;* website: *diamondaircraft.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2023–2143.

FOR FURTHER INFORMATION CONTACT: Penelope Trease, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (303) 342–1094; email: *penelope.trease@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–2023–2143; Project Identifier MCAI–2023–00088–A'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

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

Background

The FAA issued AD 2022–21–15, Amendment 39–22214 (87 FR 67541, November 9, 2022) (AD 2022–21–15), for certain DAI Model DA 42, DA 42 NG, and DA 42 M–NG airplanes. AD 2022–21–15 was prompted by MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued EASA AD 2019–0302, dated December 13, 2019 (EASA AD 2019–0302) to correct an unsafe condition on DAI Model DA 42, DA 42 NG, and DA 42 M–NG airplanes. EASA AD 2019–0302 described the unsafe condition as reports of a loose rudder T-yoke axle nut on DAI Model DA 42 airplanes and the need for new inspections for correct installation of the self-locking nut to the rudder T-yoke standard bolt LN 9037 (dimensions M6x90), and depending on findings, accomplishment of applicable corrective action(s) and replacement of the self-locking nut. EASA AD 2019–0302 also provided an optional terminating action for the repetitive inspections. This condition, if not detected and corrected, could lead to vertical movement of the bolt, possibly resulting in reduced rudder control of the airplane.

AD 2022–21–15 requires replacing the rudder T-yoke axle with an improved rudder T-yoke bolt. The FAA issued AD 2022–21–15 to prevent movement of the T-yoke bolt.

Actions Since AD 2022–21–15 Was Issued

Since the FAA issued AD 2022–21–15, EASA superseded EASA AD 2019–0302 and issued EASA AD 2023–0013, dated January 18, 2023 (EASA AD 2023–0013) (referred to after this as the MCAI) to correct an unsafe condition on all DAI Model DA 42, DA 42 M, DA 42 NG, and DA 42 M–NG airplanes.

The MCAI states that since EASA AD 2019–0302 was issued, DAI published revised service information to provide additional inspection and modification instructions. The MCAI requires a one-time inspection of the rudder steering bracket for insufficient edge distance or wear, replacement of rudder T-yoke standard bolt LN 9037 (dimensions M6x90) with rudder T-yoke bolt part number (P/N) D60–5320–00–32, repetitive inspections of rudder T-yoke bolt P/N D60–5320–00–32 for correct installation, corrective actions if necessary, and prohibits installation of

rudder T-yoke standard bolt LN 9037 (dimensions M6x90). The affected and serviceable parts, identified as ''bolt'' in EASA AD 2023–0013, were referred to as ''axle'' in EASA AD 2019–0302.

This condition, if not detected and corrected, could lead to blockage or loss of rudder control. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–2143.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–143/1 and DAI MSB 42NG–086/1, dated January 25, 2022 (issued as one document), published with DAI Work Instruction WI–MSB 42–143 and WI–MSB 42NG–086, Revision 3, dated November 15, 2022 (issued as one document) attached. The service bulletin specifies compliance with the work instruction, which contains procedures for inspecting the hole position and condition in the rudder steering bracket.

The FAA also reviewed Diamond Aircraft Recommended Service Bulletin DAI RSB 42–139 and DAI RSB 42NG–081, dated October 21, 2019 (issued as one document), published with DAI Work Instruction WI–RSB 42–139 and WI–RSB 42NG–081, Revision 2, dated November 15, 2022 (issued as one document) attached. The service bulletin specifies compliance with the work instruction, which contains procedures for replacement of the rudder T-yoke axle with an improved (additional retaining pin) rudder T-yoke axle.

In addition, the FAA reviewed Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–146 and DAI MSB 42NG–087, dated November 15, 2022, (issued as one document). The service bulletin specifies the serial numbers for airplanes identified as Group 2 in the requirements of this proposed AD. 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 **ADDRESSES**.

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would retain the requirement of AD 2022–21–15 to replace rudder T-yoke axle part number P/N LN 9037–M6x90 with rudder T-yoke axle P/N D60–5320–00–32. This proposed AD would require, for certain airplanes, inspecting the rudder steering bracket edge distance and depending on the inspection results, inspecting the T-yoke bolt hole for wear and play, and corrective actions if necessary. For certain airplanes, this proposed AD would also require applying torque seal marks on the T-yoke bolt head and self-locking nut. For all airplanes, this proposed AD would require repetitively inspecting the torque seal marks on the T-yoke bolt head for proper alignment, and the self-locking nut for proper installation, and corrective action if necessary. This proposed AD would also prohibit the installation of affected parts.

Differences Between This Proposed AD and the MCAI

The MCAI applies to DAI Model DA 42 M airplanes and this proposed AD does not because those airplanes do not have an FAA type certificate.

Paragraph (3) of the MCAI specifies to contact the manufacturer for repair instructions and paragraph (7) of the MCAI specifies to contact the manufacturer for corrective actions if any discrepancy is found, but for both of those corrective actions, this proposed AD would require contacting either the Manager, International Validation Branch, FAA; EASA; or Diamond's EASA Design Organization Approval (DOA) instead. If approved by the DOA, the approval must include the DOA-authorized signature.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 205 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection of rudder steering bracket edge distance.	0.25 work-hour × $85 per hour = $21.25.	$0	$21.25	$4,356.25.
Replacement of rudder t-yoke bolt P/N LN 9037 with P/N D60–5320–0032.	0.50 work-hour × $85 per hour = $42.50.	82	$124.50	$25,522.50.
Application of torque seal marks to rudder T-yoke bolt and self-locking nut.	0.75 work-hour × $85 per hour = $63.75.	15	$78.75	$16,143.75.
Repetitive inspection of torque seal marks.	0.25 work-hour × $85 per hour	0	$21.25, per inspection	$4,356.25, per inspection.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Inspection of rudder steering bracket hole for wear and play, if edge distance is equal to or greater than 11 millimeters.	0.50 work-hour × $85 per hour = $42.50	$0	$42.50

Since the replacement or repair instructions could vary significantly from airplane to airplane if discrepancies are found during the inspections, the FAA has no data to determine the number of airplanes that would need follow-on actions or what the cost per airplane would be.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2022–21–15, Amendment 39–22214 (87 FR 67541, November 9, 2022); and

■ b. Adding the following new airworthiness directive:

Diamond Aircraft Industries GmbH: Docket No. FAA–2023–2143; Project Identifier MCAI–2023–00088–A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 26, 2023.

(b) Affected ADs

This AD replaces AD 2022–21–15, Amendment 39–22214 (87 FR 67541, November 9, 2022).

(c) Applicability

This AD applies to Diamond Aircraft Industries GmbH (DAI) Model DA 42, DA 42 NG, and DA 42 M–NG airplanes, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 2700, Flight Control System.

(e) Unsafe Condition

This AD was prompted by reports of a loose rudder T-yoke bolt nut, excessive wear of the hole, and insufficient hole edge margin at the rudder steering bracket. The FAA is issuing this AD to detect and correct vertical movement of the T-yoke bolt (axle). The unsafe condition, if not addressed, could lead to blockage or loss of rudder control and result in reduced control of the airplane.

(f) Compliance

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

(g) Definitions

For the purposes of this AD, the following definitions apply.

(1) Group 1 airplanes: Airplanes with serial numbers specified in Technical Details, section I.2, of Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–143/1 and DAI MSB 42NG–086/1, dated January 25, 2022 (issued as one document), published with DAI Work Instruction WI–MSB 42–143 and WI–MSB 42NG–086, Revision 3, dated November 15, 2022 (issued as one document) attached.

(2) Group 2 airplanes: Airplanes with serial numbers specified in Technical Details, section I.2, of Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–146 and DAI MSB 42NG–087, dated November 15, 2022, (issued as one document).

(3) Group 3 airplanes: Airplanes that are not in Group 1 or Group 2.

(4) Depending on the serial number, a Group 1 airplane can also be a Group 2 airplane.

(h) Inspections and Corrective Actions

For Group 1 and Group 2 airplanes: Do the inspection required by paragraph (h)(1) of this AD at the compliance time specified in paragraph (h)(1) of this AD and the applicable corrective actions specified in paragraphs (h)(2) through (4) of this AD at the applicable compliance times specified in paragraphs (h)(2) through (4) of this AD.

(1) Within 200 hours time-in-service (TIS) or 9 months after the effective date of this AD, whichever occurs first, inspect the rudder steering bracket edge distance by measuring in accordance with step 6 of the Instructions, Section III, in Diamond Aircraft Work Instruction WI–MSB 42–143 and WI–MSB 42NG–086, Revision 3, dated November 15, 2022 (issued as one document) attached to Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–143/1 and DAI MSB 42NG–086/1, dated January 25, 2022 (issued as one document).

(2) If, during the inspection required by paragraph (h)(1) of this AD, the measured distance is equal to or greater than 11 millimeters (mm), before further flight, inspect the hole in the rudder steering bracket for wear and play in accordance with step 11 of the Instructions, Section III, in Diamond Aircraft Work Instruction WI–MSB 42–143 and WI–MSB 42NG–086, Revision 3, dated November 15, 2022 (issued as one document) attached to Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–143/1 and DAI MSB 42NG–086/1, dated January 25, 2022 (issued as one document).

(3) If, during the inspection required by paragraph (h)(1) of this AD, the measured distance is less than 11 mm, before further flight, contact the Manager, International Validation Branch, FAA; the European Union Aviation Safety Agency (EASA); or Diamond's EASA Design Organization Approval (DOA) for repair instructions, and within the compliance time specified therein, complete the repair. If approved by the DOA, the approval must include the DOA-authorized signature.

(4) If, during the inspection required by paragraph (h)(2) of this AD, a worn or enlarged hole is found on the rudder steering bracket, or if the T-yoke bolt is found to have play, before further flight, contact the Manager, International Validation Branch, FAA; EASA; or Diamond's EASA DOA for instructions (repair or replacement of the rudder steering bracket), and within the compliance time specified therein, do the instructions. If approved by the DOA, the approval must include the DOA-authorized signature.

(i) Replacement

For Group 2 airplanes: Concurrently with the inspection required by paragraph (h)(1) of this AD, replace the rudder T-yoke bolt part number (P/N) LN 9037–M6x90 with rudder T-yoke bolt P/N D60–5320–00–32, and apply torque seal marks on the rudder T-yoke bolt head and self-locking nut, in accordance with steps 14, 15, and 18 of the Instructions, Section III, in Diamond Aircraft Work

Instruction WI–RSB 42–139 and WI–RSB 42NG–081, Revision 2, dated November 15, 2022 (issued as one document) attached to Diamond Aircraft Recommended Service Bulletin DAI RSB 42–139 and DAI RSB 42NG–081, dated October 21, 2019 (issued as one document).

(j) Repetitive Inspections

(1) For Group 1 and Group 2 airplanes: Within 200 hours TIS after the inspection required by paragraph (h)(1) of this AD and, thereafter, at intervals not to exceed 200 hours TIS, inspect the torque seal marks on the T-yoke bolt head and self-locking nut for proper alignment.

Note 1 to paragraph (j)(1): This can be accomplished using DAI Maintenance Manual (AMM) Temporary Revision (TR) AMM–TR–MÄM–42–1213/a, dated June 7, 2022 (DAI AMM TR AMM–TR–MÄM–42–1213/a).

(2) For Group 3 airplanes: Within 200 hours TIS after the effective date of this AD, and thereafter at intervals not to exceed 200 hours TIS, inspect the torque seal marks on the T-yoke bolt head and self-locking nut for proper alignment.

Note 2 to paragraph (j)(2): This can be accomplished using DAI AMM TR AMM–TR–MÄM–42–1213/a.

(3) For all airplanes: If, during any inspection required by paragraph (j)(1) or (j)(2) of this AD, it is found that the torque seal marks are not properly aligned, before further flight, contact the Manager, International Validation Branch, FAA; EASA; or Diamond's EASA DOA for approved repair instructions, and within the compliance time specified therein, accomplish those instructions accordingly. If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Parts Installation Prohibition

For all airplanes: As of the effective date of this AD, do not install on any airplane a rudder T-yoke bolt P/N LN 9037–M6x90.

(l) Credit for Previous Actions

(1) You may take credit for the actions required by paragraphs (h)(1) and (2) of this AD if the actions were done before the effective date of this AD using any of the work instructions specified in paragraphs (l)(1)(i), (ii), or (iii) of this AD.

(i) Diamond Aircraft Work Instruction WI–MSB 42–143 and WI–MSB 42NG–086, Revision 0, dated December 23, 2021 (issued as one document) attached to Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–143 and DAI MSB 42NG–086, dated December 23, 2021 (issued as one document).

(ii) Diamond Aircraft Work Instruction WI–MSB 42–143 and WI–MSB 42NG–086, Revision 1, dated January 25, 2022 (issued as one document) attached to Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–143/1 and DAI MSB 42NG–086/1, dated January 25, 2022 (issued as one document).

(iii) Diamond Aircraft Work Instruction WI–MSB 42–143 and WI–MSB 42NG–086, Revision 2, dated March 10, 2022 (issued as one document) attached to Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–143/1 and DAI MSB 42NG–086/1, dated January 25, 2022 (issued as one document).

(2) You may take credit for the rudder T-yoke bolt replacement required by paragraph (i) of this AD if that action was done before the effective date of this AD using the Diamond Aircraft Work Instruction WI–RSB 42–139 and WI–RSB 42NG–081, Revision 1, dated October 24, 2019 (issued as one document) attached to Diamond Aircraft Recommended Service Bulletin DAI RSB 42–139 and DAI RSB 42NG–081, dated October 21, 2019 (issued as one document).

(m) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (n)(2) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(n) Additional Information

(1) Refer to EASA AD 2023–0013, dated January 18, 2023, for related information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2023–2143.

(2) For more information about this AD, contact Penelope Trease, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (303) 342–1094; email: *penelope.trease@faa.gov.*

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(3) and (4) of this AD.

(o) Material Incorporated by Reference

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

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

(i) Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–143/1 and DAI MSB 42NG–086/1, dated January 25, 2022 (issued as one document), published with DAI Work Instruction WI–MSB 42–143 and WI–MSB 42NG–086, Revision 3, dated November 15, 2022 (issued as one document) attached.

(ii) Diamond Aircraft Mandatory Service Bulletin DAI MSB 42–146 and DAI MSB 42NG–087, dated November 15, 2022, (issued as one document).

(iii) Diamond Aircraft Recommended Service Bulletin DAI RSB 42–139 and DAI RSB 42NG–081, dated October 21, 2019 (issued as one document), published with DAI Work Instruction WI–RSB 42–139 and WI–RSB 42NG–081, Revision 2, dated November 15, 2022 (issued as one document) attached.

(3) For service information identified in this AD, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A–2700 Wiener Neustadt, Austria; phone: +43 2622 26700; email: *airworthiness-austria@diamondaircraft.com;* website: *diamondaircraft.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2023–2143.

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

Issued on October 30, 2023.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–24328 Filed 11–7–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Parts 345 and 545

[Docket No. BOP–1181–P]

RIN 1120–AB81

Reservation of Funds for Reentry Under the First Step Act

AGENCY: Bureau of Prisons, Department of Justice.

ACTION: Proposed rule.

SUMMARY: The Bureau of Prisons (BOP) proposes to add a regulation implementing a provision of the First Step Act (FSA) that requires Federal Prison Industries (FPI) and the BOP to reserve a portion of the compensation inmates would otherwise receive for working to assist these inmates with costs associated with release from prison upon completion of their sentence through release from custody, placement in pre-release custody (*e.g.,* home confinement or Residential Reentry Center), or conditional release.

DATES: Electronic comments must be submitted, and written comments must be postmarked, no later than 11:59 p.m. Eastern Time on January 8, 2024.

ADDRESSES: Please submit electronic comments through the *regulations.gov* website, or mail written comments to the Legislative & Correctional Issues Branch, Office of General Counsel, Bureau of Prisons, 320 First Street NW, Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Daniel J. Crooks III, Assistant General Counsel, Federal Bureau of Prisons, (202) 353–4885.

SUPPLEMENTARY INFORMATION: Please note that all comments received are considered part of the public record and made available for public inspection online at *www.regulations.gov.* If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also locate all the personal identifying information you do not want posted online in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment contains so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *www.regulations.gov.*

Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** section.

I. Discussion of the Proposed Rule

In this document, the BOP proposes to modify regulations on compensation for FPI inmate workers in 28 CFR part 345 and on inmate work and performance pay in part 545 to conform with recent legislative changes enacted in the First Step Act of 2018 (FSA), Public Law 115–391, December 21, 2018, 132 Stat 5194. Section 605(c) of the FSA amends 18 U.S.C. 4126(c)(4) to indicate that inmates compensated under this section shall have at least 15 percent of their compensation reserved and made available to assist them with costs associated with release from prison.

The section amended by the FSA, 18 U.S.C. 4126, is entitled ''Prison Industries Fund; use and settlement of accounts,'' and the amended subparagraph (c) refers to ''Federal Prison Industries'' (FPI) as the ''corporation'' and the ''Prison Industries Fund'' as ''the fund.'' *See* 18 U.S.C. 4126(a). Subparagraph (c)(4) was amended to indicate that FPI ''is authorized to employ the fund . . .'' to pay ''compensation to inmates employed in any industry, or performing outstanding services in institutional operations, not less than 15 percent of such compensation for any inmate shall be reserved in the fund or a separate account and made available to assist the inmate with costs associated with release from prison . . . .'' *See* 18 U.S.C. 4126(c)(4).

The FSA therefore authorizes FPI to pay inmates who are ''employed in any industry.'' As provided in 28 CFR 345.10, the BOP strives to provide work to all inmates confined in BOP facilities to the extent practicable in order to allow inmates to gain knowledge, skills, and work habits to assist them upon release. Although there is no statutory requirement that inmates be paid for work in an industrial assignment, 18 U.S.C. 4126 provides for discretionary compensation to inmates employed by FPI. Section 345.50 further indicates that, in accordance with 18 U.S.C. 4126, FPI provides compensation to FPI inmate workers.

The FSA also amended 18 U.S.C. 4126(c)(4) by directing that ''not less than 15 percent'' of compensation paid to inmates ''performing outstanding services in institutional operations'' should also be ''reserved in the fund or a separate account and made available to assist the inmate with costs associated with release from prison.''

The new provision added by the FSA in 18 U.S.C. 4126(c)(4) requires the reservation of 15 percent of ''such compensation'' to be made available for an inmate's costs associated with prison release. Therefore, the FSA mandates that FPI must reserve 15 percent of the compensation that is paid to inmates employed by FPI, under 28 CFR part 345, to be made available to those inmates for costs associated with their release from prison. The FSA further mandates that the BOP must reserve 15 percent of performance pay, bonus pay, and special bonus pay, under 28 CFR part 545, to be made available to those inmates for costs associated with their release from prison.

The BOP now proposes to amend 28 CFR 345.51 regarding FPI pay, and 545.26(e) through (g) regarding inmate performance pay, bonus pay, and special bonus pay, to add provisions indicating that 15 percent of an inmate's pay, or other amount as set by statute, will be reserved (*i.e.,* encumbered) to assist the inmate with costs associated with release from prison. Specifically, the reserved funds will be made available to the inmate upon completion of their sentence through release from custody, placement in pre-release custody (*e.g.,* home confinement or Residential Reentry Center), or conditional release. Holding the funds until the inmate leaves BOP secure custody via one of the previously mentioned ways will ensure the availability of those funds on the inmate's first day of reentry, giving full effect to Congress's directive that these funds be reserved to help inmates with costs they will incur once they release from prison.

II. Regulatory Analyses

Executive Orders 12866 and 13563 (Regulatory Review)

This proposed rule does not fall within a category of actions that the Office of Management and Budget (OMB) has determined constitutes a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and, accordingly, it was not reviewed by OMB. The economic impact of this proposed rule is limited to an existing BOP program that applies to sentenced inmates in the custody of the Federal Bureau of Prisons, and does not apply to inmates in study/observation; pretrial detainees; or inmates in holdover status pending designation.

This rulemaking is necessary to implement section 605(c) of the FSA, codified at 18 U.S.C. 4126(c)(4). The reserved funds will remain in the existing Inmate Deposit Fund until an inmate completes their sentence through release from custody, placement in pre-release custody (*e.g.,* home confinement or Residential Reentry Center), or conditional release.

One of the expected benefits of this regulation is that inmates will be more financially prepared for reentry. The amount each inmate saves for reentry will vary widely based on the amount of time the inmate works in FPI, or works an institution job and receives performance, bonus, or special bonus pay. As a result of inmates' having additional reentry funds, the public may save on indirect societal costs related to inmate releases into the community. However, at this time the BOP cannot, with any degree of accuracy, estimate the monetary value of the costs and savings of this rulemaking. However, the BOP would expect any anticipated costs and savings generated by this rulemaking to have minimal effect on the economy.

This proposed rule does not fall within a category of actions that the Office of Management and Budget (OMB) has determined constitutes a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and, accordingly, it was not reviewed by OMB. The economic impact of this proposed rule is limited to an existing BOP program that applies to sentenced inmates in the custody of the Federal Bureau of Prisons, and does not apply to inmates in study/observation; pretrial detainees; or inmates in holdover status pending designation.

Executive Order 13132 (Federalism)

This regulation will not have substantial direct effect on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, under Executive Order 13132, we determine that this regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988 (Plain Language)

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation and by approving it certifies that it will not have a significant economic impact upon a substantial number of small entities for the following reasons: This regulation pertains to Federal inmates who work in FPI, or who work institution jobs and receive performance, bonus, or special bonus pay, and its economic impact is limited to moneys under the control of FPI or BOP.

Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year (adjusted for inflation), and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This regulation is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 804.

List of Subjects in 28 CFR Parts 345 and 545

Prisoners.

Colette S. Peters,

Director, Federal Bureau of Prisons.

Under rulemaking authority vested in the Attorney General in 5 U.S.C. 301; 28 U.S.C. 509, 510 and delegated to the Director, Federal Bureau of Prisons in 28 CFR 0.96, we propose to amend 28 CFR parts 345 and 545 as follows:

PART 345—FEDERAL PRISON INDUSTRIES (FPI) INMATE WORK PROGRAMS

■ 1. The authority citation for part 345 continues to read as follows:

Authority: 18 U.S.C. 4126, 28 CFR 0.99, and by resolution of the Board of Directors of Federal Prison Industries, Inc.

■ 2. Amend § 345.51 by redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5), respectively, and adding a new paragraph (b)(3) to read as follows:

§ 345.51 Inmate pay.

* * * * *

(b) * * *

(3) Fifteen percent of each inmate's pay under this part, or other amount as set by statute, will be reserved to assist the inmate with costs associated with release from prison. The reserved funds will be made available to the inmate upon completion of their sentence through release from custody, placement in pre-release custody (*e.g.,* home confinement or Residential Reentry Center), or conditional release.

* * * * *

PART 545—WORK AND COMPENSATION

■ 3. The authority citation for part 545 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3013, 3571, 3572, 3621, 3622, 3624, 3663, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4126, 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

■ 4. Amend § 545.26, by adding paragraph (e)(4), and revising paragraphs (f) and (g) to read as follows:

§ 545.26 Performance pay provisions.

* * * * *

(e) * * *

(4) Fifteen percent of an inmate's pay under this paragraph, or other amount as set by statute, shall be reserved to assist the inmate with costs associated with release from prison. The reserved funds will be made available to the inmate upon completion of their sentence through release from custody, placement in pre-release custody (*e.g.,* home confinement or Residential Reentry Center), or conditional release.

(f) *Bonus pay.* (1) An inmate worker or program participant may receive special bonus pay based on the inmate's exceptional accomplishments or appreciable contributions to the work assignment. For example, an inmate who works in excess of the scheduled work day may qualify for bonus pay.

(2) When the supervisor of an inmate worker or program participant believes the inmate has performed exceptionally well, the supervisor may forward a written recommendation that the inmate received a special bonus, along with justification for the special bonus recommendation, to the Department Head for approval.

(3) Fifteen percent of an inmate's pay under this paragraph, or other amount as set by statute, shall be reserved to assist the inmate with costs associated with release from prison. The reserved funds will be made available to the inmate upon completion of their sentence through release from custody, placement in pre-release custody (*e.g.,* home confinement or Residential Reentry Center), or conditional release.

(g) *Special bonus pay.* (1) An inmate may receive special bonus pay based on the inmate's exceptional work in a temporary job assignment that has been previously identified by the Warden, and approved by the Regional Director, as critical to the institution.

(2) When the supervisor of an inmate worker believes the inmate has performed exceptionally well, the supervisor may forward a written recommendation that the inmate received a special bonus, along with justification for the special bonus recommendation, to the Department Head for approval.

(3) Fifteen percent of an inmate's pay under this paragraph, or other amount as set by statute, shall be reserved to assist the inmate with costs associated with release from prison. The reserved funds will be made available to the inmate upon completion of their sentence through release from custody, placement in pre-release custody (*e.g.,* home confinement or Residential Reentry Center), or conditional release.

* * * * *

[FR Doc. 2023–24619 Filed 11–7–23; 8:45 am]

BILLING CODE 4410–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 16

[EPA–HQ–OMS–2023–0020; FRL–10620–02–OMS]

Privacy Act Regulations for EPA–100

AGENCY: Office of Inspector General, Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is proposing to revise the Agency's Privacy Act regulations to exempt a new system of records, EPA–100, OIG Data Analytics Enterprise, from certain requirements of the Privacy Act. In this rulemaking, the Agency proposes to exempt portions of this system from certain provisions of the Privacy Act because of law enforcement requirements and to avoid interference during the conduct of criminal, civil, or administrative actions or investigations. Additionally, EPA is proposing to revise the Agency's Privacy Act regulations to update the names of systems of records with general and specific exemptions, change wording to reflect that the Office of Inspector General (OIG) is an independent component of EPA, incorporate the revised citation for the Inspector General Act of 1978 and to remove specific systems of record which are no longer exempt.

DATES: Persons wishing to comment on this system of records notice must do so by December 8, 2023. New routine uses for this modified system of records will be effective December 8, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OMS–2023–0020, at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Daniel Porter, Director, Data Analytics Directorate, Office of Inspector General, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20004; telephone number: 202–309–6449; email address: *oig.data_analytics@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is EPA issuing this proposed rule?

The EPA proposes to revise the Agency's Privacy Act regulations in order to exempt a new system of records, EPA–100, the OIG Data Analytics Enterprise, from certain requirements of the Privacy Act. The EPA has published a direct final rule exempting this system of records in the ''Rules and Regulations'' section of this **Federal Register** because it views this as a noncontroversial action and anticipates no adverse comment. EPA explains its reasons for the direct final rule in the preamble to that rule. If EPA receives no adverse comment, it will not take further action on this proposed rule.

If EPA receives adverse comment, it will withdraw the direct final rule and the rule will not take effect. EPA will address public comments in any subsequent final rule based on this proposed rule. EPA does not intend to institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information, please see the information provided in the **ADDRESSES** section of this document.

EPA is also proposing to revise the Agency's Privacy Act regulations to update the names of systems of records with general and specific exemptions. Specifically, 40 CFR 16.11, will be modified to update the name of EPA–17 from OCEFT Criminal Investigative Index and Files to Online Criminal Enforcement Activities Network (OCEAN) and EPA–40 from Inspector General's Operation and Reporting (IGOR) System Investigative Files to Inspector General Enterprise Management System (IGEMS) Investigative Module and to add EPA–100 OIG Data Analytics Enterprise. Likewise, 40 CFR 16.12 will also be modified to update the names of EPA–17 from OCEFT Criminal Investigative Index and Files to Online Criminal Enforcement Activities Network (OCEAN), EPA–21 from External Compliance Program Discrimination Complaint Files to External Compliance Case Tracking System (EXCATS), EPA–30 from OIG Hotline Allegation System to Inspector General Enterprise Management System (IGEMS) Hotline Module and EPA–40 from Inspector General's Operation and Reporting (IGOR) System Investigative Files to Inspector General Enterprise Management System (IGEMS) Investigative Module. Additionally, 16.12 will be modified to add EPA–100 OIG Data Analytics Enterprise and to remove reference to EPA–41 because the system of records is no longer exempt.

II. General Information

The EPA will use this system of records to develop data models and analyses in order to identify fraud, waste and abuse, and programmatic problems and deficiencies. This system of records will allow the EPA OIG to identify correlations between existing EPA data sets and other government agency data sets so as to identify patterns and correlations that indicate fraud and issues of program waste and abuse. EPA OIG will apply analytics and data modeling principles within this system of records to identify problems or failures in the implementation or performance of internal controls within the EPA. The records may be used in the course of performing audits, evaluations, and inspections; investigating individuals and entities suspected of criminal, civil, or administrative misconduct and in supporting related judicial and administrative proceedings; or in conducting preliminary inquiries undertaken to determine whether to commence an audit, evaluation, inspection, or investigation.

The EPA compiles and maintains the records in the OIG Data Analytics Enterprise for use in criminal and civil investigations and actions. This system of records, EPA–100, is maintained by the Office of Inspector General. This component of EPA performs as its principal function, activities pertaining to the enforcement of criminal laws.

The Privacy Act allows Federal agencies to exempt eligible records in a system of records from certain provisions of the Act, including those that provide individuals with a right to request access to and amendment of their own records. If an agency intends to exempt a particular system of records, it must first go through the rulemaking process pursuant to 5 U.S.C. 553(b)(1)–(3), (c), and (e). This proposed rule explains why an exemption is being claimed for this system of records and

invites public comment, which EPA will consider before the issuance of a final rule implementing the exemption.

Under 5 U.S.C. 552a(j)(2), the head of any agency may exempt any system of records within the agency from certain provisions of the Privacy Act, if the agency or component that maintains the system performs as its principal function any activities pertaining to the enforcement of criminal laws. The Inspector General Act mandates that the Inspector General recommend policies for, and conduct, supervise, and coordinate activities in the Agency and between the Agency and other Federal, State, and local government agencies with respect to all matters relating to the prevention and detection of fraud in programs and operations administered or financed by the Agency, and to the identification and prosecution of participants in such fraud. Under the Inspector General Act, whenever the Inspector General has reasonable grounds to believe that there has been a violation of Federal criminal law, the Inspector General must report the matter expeditiously to the Attorney General. In addition to these principal functions pertaining to the enforcement of criminal laws, the Inspector General may receive and investigate complaints on information from various sources concerning the possible existence of activities constituting violations of law, rules, or regulations, or mismanagement, gross waste of funds, abuses of authority, or substantial and specific danger to the public health and safety. To the extent criminal law enforcement information is contained in the system as enumerated in 5 U.S.C. 552a(j)(2), the provisions of the Privacy Act from which exemptions are claimed under 5 U.S.C. 552a(j)(2) are as follows: 5 U.S.C. 552a(c)(3) and (4); 5 U.S.C. 552a(d); 5 U.S.C. 552a(e)(1), (2) and (3); 5 U.S.C. 552a(e)(4)(G) and (H); 5 U.S.C. 552a(e)(5) and (8); 5 U.S.C. 552a(f)(2) through (5); and 5 U.S.C. 552a(g).

EPA is claiming the above exemptions for the following reasons:

(1) From subsection (c)(3), because making available to a named individual an accounting of disclosures of records concerning him/her/them could reveal investigative interest on the part of EPA and/or the Department of Justice. This could allow record subjects to impede the investigation, *e.g.,* destroy evidence, intimidate potential witnesses, or flee the area to avoid inquiries or apprehension by law enforcement personnel. More broadly, the application of this provision could reveal the OIG's investigative interests, which could compromise those investigative interests. Further, such a disclosure could reveal the identity of a confidential source and hamper the Agency's investigation.

(2) From subsection (c)(4), which concerns providing notice to others regarding corrections or disputed information in accordance with subsection (d) of the Privacy Act, because no access to these records is available under subsection (d) of the Act.

(3) From subsection (d), which requires an agency to permit an individual to access, contest or request amendment of records pertaining to him/her/them, because the records contained in this system relate to official Federal investigations. Individual access to these records could compromise ongoing investigations, reveal confidential informants and/or sensitive investigative techniques used in particular investigations, or constitute unwarranted invasions of the personal privacy of third parties who are involved in a certain investigation.

(4) From subsection (e)(1), which requires an agency to maintain only relevant and necessary information about an individual, because the relevance or necessity of information obtained in the course of a law enforcement investigation is not always known when collected. Material that may seem unrelated, irrelevant, or incomplete when collected may take on added meaning or significance as the investigation progresses. Also, in the interest of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of criminal activity. Therefore, it would impede the investigative process if it were necessary to assure the relevance and necessity of all information obtained.

(5) From subsection (e)(2), which requires an agency to collect information to the greatest extent practicable directly from the subject individual when the information may result in adverse determinations about the individual's rights, benefits, or privileges under Federal programs. Application of this provision could impair investigations and law enforcement by alerting the subject of the investigation to the existence of the investigation. Further, compliance with the requirements of this subsection during the course of an investigation could impede the information gathering process or cause the destruction of evidence, thus hampering the investigation.

(6) From subsection (e)(3), which requires an agency to inform those supplying information of its authority to collect the information, its plans for using or sharing that information, and the effects of not providing the requested information. The application of this provision could provide the subject of the investigation with substantial information about the nature of the investigation, which could interfere with the investigation. To comply with the requirements of this subsection during the course of an investigation could impede the information gathering process especially when undercover operations or confidential sources are used, thus hampering the investigation.

(7) From subsections (e)(4)(G) and (H), which require an agency to publish—in the **Federal Register**—procedures concerning access to records, because no access to these records is available under subsection (d) of the Privacy Act, for the reasons explained above in the discussion of subsection (d).

(8) From subsection (e)(5), which requires an agency to maintain its records with accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual, because it is not possible to determine in advance what information is accurate, relevant, timely, and complete. Facts are first gathered and then placed into a logical order to prove or disprove objectively the criminal behavior of an individual. Material that may seem unrelated, irrelevant, or incomplete when collected may take on added meaning or significance as the investigation progresses. The restrictions of this provision could interfere with the preparation of a complete investigative report, thereby impeding effective law enforcement.

(9) From subsection (e)(8), which requires notice to an individual whenever a record on such individual is made available to others under compulsory legal process, because complying with this provision could prematurely reveal an ongoing criminal investigation to the subject of the investigation.

(10) From subsections (f)(2), (f)(3), (f)(4) and (f)(5), concerning agency rules for obtaining access to records under subsection (d), because this system is exempt from the access and amendment provisions of subsection (d). Since EPA is proposing that this system of records be exempt from subsection (d) of the Act, concerning access to records, the requirements of subsections (f)(2) through (5) of the Act, concerning agency rules for obtaining access to such records, are inapplicable and are exempted to the extent that this system of records is exempted from subsection (d) of the Act.

(11) From subsection (g), which provides for civil remedies if an agency fails to comply with certain requirements of the Act applicable to a nonexempt system of records, because EPA is proposing that this system of records is exempt from subsections (c)(3) and (4); (d); (e)(1), (2), (3), (4)(G) and (H), (5), and (8); and (f)(2), through (5) of the Act. The provisions of subsection (g) of the Act are inapplicable to the extent that this system of records is exempted from those subsections of the Act.

The EPA also compiles and maintains the records in the OIG Data Analytics Enterprise for use in civil and administrative investigations and actions. In those cases, the system again is maintained by the Office of Inspector General. The statute at 5 U.S.C. 552a(k)(2) states that the head of an agency may promulgate regulations to exempt the system from certain provisions of the Act if the system ''is investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2)'' of 5 U.S.C. 552a. Accordingly, to the extent investigatory records are not covered under the exemptions in subsection (j)(2), the following provisions of the Privacy Act are exempt pursuant to 5 U.S.C. 552a(k)(2): 5 U.S.C. 552a(c)(3), 5 U.S.C. 552a(d), 5 U.S.C. 552a(e)(1), 5 U.S.C. 552a(e)(4)(G) and (H) and 5 U.S.C. 552a(f)(2) through (5):

(1) From subsection (c)(3) because making available to named individual an accounting of disclosures of records concerning him/her/them could reveal investigative interest on the part of EPA and/or the Department of Justice. This could allow record subjects to impede the investigation, *e.g.,* destroy evidence, intimidate potential witnesses, or flee the area to avoid inquiries or apprehension by law enforcement personnel. More broadly, the application of this provision could reveal the OIG's investigative interests, which could compromise those investigative interests. Further, such a disclosure could reveal the identity of a confidential source and hamper the Agency's investigation.

(2) From subsection (d), which requires an agency to permit an individual to access, contest or request amendment of records pertaining to him/her/them, because the records contained in this system relate to official Federal investigations. Individual access to these records could compromise ongoing investigations, reveal confidential informants and/or sensitive investigative techniques used in particular investigations, or constitute unwarranted invasions of the personal privacy of third parties who are involved in a certain investigation.

(3) From subsection (e)(1), which requires each agency to maintain only such information about an individual as is relevant and necessary to accomplish a purpose of the agency, because in the course of law enforcement investigations information may occasionally be obtained or introduced the accuracy of which is unclear or which is not strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of criminal activity. Moreover, it would impede any investigative process, whether civil or criminal, if it were necessary to assure the relevance, accuracy, timeliness and completeness of all information obtained.

(4) From subsections (e)(4)(G) and (H), which require an agency to publish—in the **Federal Register**—procedures concerning access to records, because no access to these records is available under subsection (d) of the Privacy Act, for the reasons explained above in the discussion of subsection (d).

(5) From subsection (f)(2), (f)(3), (f)(4) and (f)(5), concerning agency rules for obtaining access to records under subsection (d), because this system is exempt from the access and amendment provisions of subsection (d). Since EPA is proposing to determine that this system of records is exempt from subsection (d) of the Act, concerning access to records, the requirements of subsections (f)(2) through (5) of the Act, concerning agency rules for obtaining access to such records, are inapplicable and are exempted to the extent that this system of records is exempted from subsection (d) of the Act.

The EPA also compiles and maintains the records in the OIG Data Analytics Enterprise, EPA–100, for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information. In those cases, the system again is maintained by the Office of Inspector General. 5 U.S.C. 552a(k)(5) states that the head of any agency may by rule exempt any system of records within the agency from certain provisions of the Privacy Act, if the system of records is investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence. Accordingly, to the extent any records would disclose source-identifying information, all such information in the OIG Data Analytics Enterprise, EPA–100, are exempt from 5 U.S.C. 552a(c)(3) and 5 U.S.C. 552a(d):

(1) From subsection (c)(3) because making available to named individual an accounting of disclosures of records concerning him/her/them could reveal investigative interest on the part of EPA and/or the Department of Justice. This could allow record subjects to impede the investigation, *e.g.,* destroy evidence, intimidate potential witnesses, or flee the area to avoid inquiries or apprehension by law enforcement personnel. More broadly, the application of this provision could reveal the OIG's investigative interests, which could compromise those investigative interests. Further, such a disclosure could reveal the identity of a confidential source and hamper the Agency's investigation.

(2) From subsection (d), which requires an agency to permit an individual to access, contest or request amendment of records pertaining to him/her/them, because the records contained in this system relate to official Federal investigations. Individual access to these records could compromise ongoing investigations, reveal confidential informants and/or sensitive investigative techniques used in particular investigations, or constitute unwarranted invasions of the personal privacy of third parties who are involved in a certain investigation.

III. Statutory and Executive Orders Reviews

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

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

This action was submitted to the Office of Management and Budget (OMB) for review and reviewed without comment.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This action contains no provisions constituting a collection of information under the PRA.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

E. Executive Order 13132 (Federalism)

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 16

Environmental protection, Administrative practice and procedure, Confidential business information, Government employees, Privacy.

Kimberly Y. Patrick,

Principal Deputy Assistant Administrator, Office of Mission Support.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 16 as follows:

PART 16—IMPLEMENTATION OF PRIVACY ACT OF 1974

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552a (as revised).

■ 2. Amend § 16.11 by:
■ a. Revising paragraphs (a) and (c)(2);
■ b. Adding paragraph (c)(6); and
■ c. Revising paragraphs (d) and the introductory text of paragraph (e);

The revisions and addition read as follows:

§ 16.11 General exemptions.

(a) *Systems of records affected.* (1) EPA–17 Online Criminal Enforcement Activities Network (OCEAN).

(2) EPA–40 Inspector General Enterprise Management System (IGEMS) Investigative Module.

(3) EPA–63 eDiscovery Enterprise Tool Suite.

(4) EPA–79 NEIC Master Tracking System.

(5) EPA–100 OIG Data Analytics Enterprise.

* * * * *

(c) * * *

(2) The Agency's system of records, EPA–40 is maintained by the Office of Inspector General (OIG), an independent component of EPA that performs as its principal function activities pertaining to the enforcement of criminal laws. Authority for the criminal law enforcement activities of the OIG's Office of Investigations is the Inspector General Act of 1978, as amended, 5 U.S.C. 401–424.

* * * * *

(6) The Agency's system of records, EPA–100 system of records is maintained by the Office of Inspector General, an independent component of EPA which performs as its principal function activities pertaining to the enforcement of criminal laws. Authority for the criminal law enforcement activities of the Office of Inspector General is the Inspector General Act of 1978, as amended, 5 U.S.C. 401–424.

(d) *Scope of exemption.* EPA systems of records 17, 40, 63, 79, and 100 are exempted from the following provisions of the PA: 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (2), (3), (4)(G), and (H), (5), and (8); (f)(2) through (5); and (g). To the extent that the exemption for EPA systems of records 17, 40, 63, 79 and 100 claimed under 5 U.S.C. 552a(j)(2) is held to be invalid, then an exemption under 5 U.S.C. 552a(k)(2) is claimed for these systems of records from (c)(3), (d), (e)(1), (e)(4)(G) and (H), and (f)(2) through (5). For Agency's system of records, EPA system 40, an exemption is separately claimed under 5 U.S.C. 552(k)(5) from (c)(3), (d), (e)(1), (e)(4)(G), (4)(H), and (f)(2) through (5). For Agency's system of records, EPA system 100, an exemption is separately claimed under 5 U.S.C. 552(k)(5) from (c)(3) and (d).

(e) *Reasons for exemption.* EPA systems of records 17, 40, 63, 79, and 100 are exempted from the provisions of the PA in paragraph (d) of this section for the following reasons:

* * * * *

■ 3. Amend § 16.12 by revising paragraph (a)(1), the first sentence in paragraph (a)(4)(i), paragraph (a)(4)(iii), the introductory text of paragraph (a)(5), paragraphs (b)(1) and (4), and the introductory text of paragraph (b)(5) to read as follows:

§ 16.12 Specific exemptions.

(a) * * *

(1) *Systems of records affected.* (i) EPA–17 Online Criminal Enforcement Activities Network (OCEAN).

(ii) EPA–21 External Compliance Case Tracking System (EXCATS).

(iii) EPA–30 Inspector General Enterprise Management System (IGEMS) Hotline Module.

(iv) EPA–40 Inspector General Enterprise Management System (IGEMS) Investigative Module.

(v) EPA–63 eDiscovery Enterprise Tool Suite.

(vi) EPA–79 NEIC Master Tracking System.

(vii) EPA–100 OIG Data Analytics Enterprise.

* * * * *

(4) * * *

(i) EPA systems of records 17, 30, 40, 63, 79, and 100 are exempted from the

following provisions of the PA, subject to the limitations set forth in 5 U.S.C. 552a(k)(2): 5 U.S.C. 552a(c)(3); (d); (e)(1), (4)(G) and (4)(H); and (f)(2) through (5). * * *

* * * * *

(iii) EPA–17 Online Criminal Enforcement Activities Network (OCEAN), EPA–40 Inspector General Enterprise Management System (IGEMS) Investigative Module, EPA–79 NEIC Master Tracking System, and EPA–100 OIG Data Analytics Enterprise are exempted under 5 U.S.C. 552a(j)(2), and these systems are exempted under 5 U.S.C. 552a(k)(2) only to the extent that the (j)(2) exemption is held to be invalid.

(5) *Reasons for exemption.* EPA systems of records 17, 21, 30, 40, 63, 79, and 100 are exempted from the provisions of the PA in paragraph (a)(4) of this section for the following reasons:

* * * * *

(b) * * *

(1) *Systems of records affected.* (i) EPA 36 Research Grant, Cooperative Agreement, and Fellowship Application Files.

(ii) EPA 40 Inspector General Enterprise Management System (IGEMS) Investigative Module.

(iii) EPA 100 OIG Data Analytics Enterprise.

* * * * *

(4) *Scope of exemption.* (i) EPA 36 and 100 are exempted from 5 U.S.C. 552a(c)(3) and (d). EPA 40 is exempted from the following provisions of the PA, subject to the limitations of 5 U.S.C. 552a(k)(5); 5 U.S.C. 552a(c)(3); (d); (e)(1), (4)(H); and (f)(2) through (5).

(ii) To the extent that records in EPA 40 and 100 reveal a violation or potential violation of law, then an exemption under 5 U.S.C. 552a(k)(2) is also claimed for these records. EPA 40 and 100 are also exempt under 5 U.S.C. 552a(j)(2).

(5) *Reasons for exemption.* EPA 36, 40, and 100 are exempted from the above provisions of the PA for the following reasons:

* * * * *

[FR Doc. 2023–24232 Filed 11–7–23; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 88, No. 215
Wednesday, November 8, 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

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 8, 2023 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Emergency Conservation Program and Biomass Crop Assistance Program.

OMB Control Number: 0560–0082.

Summary of Collection: The Farm Service Agency (FSA), in cooperation with the Natural Resources Conservation Service, the Forest Service, and other agencies and organizations, provides eligible producers and landowners cost-share incentives and technical assistance through several conservation and environmental programs to help farmers, ranchers, and other eligible landowners and operators conserve soil, improve water quality, develop forests, and rehabilitate farmland severely damaged by natural disasters authorized under the Agricultural Credit Act of 1978 (16 U.S.C. 2201–2205). FSA provides emergency funds for sharing with agricultural producers the cost of rehabilitating farmland damaged by natural disaster, and for carrying out emergency water conservation measures during periods of severe drought.

FSA is also managing the Biomass Crop Assistance Program (BCAP) authorized by Section 9010 of the Agricultural Act of 2014 (Pub. L. 113–79), which amends Title 1X of the Food, Conservation and Energy Act of 2008. BCAP regulations outlined the legislations parameters, program definitions and process for: (1) Establishing BCAP project areas; (2) Matching payment opportunity for eligible material owners and qualifying biomass conversion facilities; (3) Contracting acreage for producers in BCAP project areas; and (4) Establishment and annual production payments for producers in BCAP projects areas.

Need and Use of the Information: FSA will collect information using several forms. The collected information will be used to determine if the person, land, and practices are eligible for participation in the respective program and to receive cost-share assistance. Also, information collection from eligible biomass owners, biomass conversion facilities, and producers meeting the requirements for matching payments, annual production payment assistance, establishment payments and BCAP project area designation is necessary in order to ensure the financial accountability needed to operate and administer the BCAP. Without the information, FSA will not be able to make eligibility determinations and compute payments in a timely manner.

Description of Respondents: Farms; Business or other for profit.

Number of Respondents: 140,000.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 67,852.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–24622 Filed 11–7–23; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

The Emergency Food Assistance Program; Availability of Foods for Fiscal Year 2024

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the surplus and purchased foods that the Department expects to make available for donation to States for use in providing nutrition assistance to the needy under The Emergency Food Assistance Program (TEFAP) in Fiscal Year (FY) 2024. The foods made available under this notice must, at the discretion of the State, be distributed to eligible recipient agencies (ERAs) for use in preparing meals and/or for distribution to households for home consumption.

FOR FURTHER INFORMATION CONTACT: Ruth Decosse, Food Distribution Policy Branch, Policy Division, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, Alexandria, Virginia 22314 or telephone (617) 317–5136.

SUPPLEMENTARY INFORMATION: In accordance with the provisions set forth in the Emergency Food Assistance Act of 1983 (EFAA), 7 U.S.C. 7501, *et seq.,* and the Food and Nutrition Act of 2008, 7 U.S.C. 2036, the Department makes foods available to States for use in providing nutrition assistance to those in need through TEFAP. In accordance

with section 214 of the EFAA, 7 U.S.C. 7515, funding for TEFAP foods is allocated among States according to a formula that accounts for poverty and unemployment levels within each State. Section 214(a)(1) of the Act requires that 60 percent of each State's allocation be based on the number of people with incomes below the poverty level within the State; and section 214(a)(2) requires that the remaining 40 percent be equal to the percentage of the nation's unemployed persons within the State. State officials are responsible for establishing the network through which the foods will be used by ERAs in providing nutrition assistance to those in need and for allocating foods among those ERAs. States have full discretion in determining the amount of foods that will be made available to ERAs for use in preparing meals and/or for distribution to households for home consumption.

Surplus Foods

Surplus foods donated for distribution under TEFAP are Commodity Credit Corporation (CCC) foods purchased under the authority of section 416 of the Agricultural Act of 1949, 7 U.S.C. 1431 (section 416) and foods purchased under the surplus removal authority of section 32 of the Act of August 24, 1935, 7 U.S.C. 612c (section 32). The types of foods typically purchased under section 416 include dairy, grains, oils, and peanut products. The types of foods purchased under section 32 include meat, poultry, fish, vegetables, dry beans, juices, and fruits.

Approximately $471.4 million in surplus foods acquired in FY 2023 are being delivered to States in FY 2024. Surplus foods currently scheduled for delivery include almonds, apples, applesauce, apricots, beans, blueberries, cherries, dates, fish, grapefruit, lamb, lentils, peaches, pistachios, plums, pork, raisins, shrimp, strawberries, and walnuts. Other surplus foods may be made available to TEFAP throughout the year. The Department would like to point out that food acquisitions are based on changing agricultural market conditions; therefore, the availability of foods is subject to change.

Purchased Foods

In accordance with section 27 of the Food and Nutrition Act of 2008, 7 U.S.C. 2036, the Secretary is directed to purchase an estimated $463.75 million worth of foods in FY 2024 for distribution through TEFAP. In addition, States will receive up to $943 million in supplemental foods and operational expenses provided under the statutory authority of the Commodity Credit Corporation. These foods are made available to States in addition to those surplus foods which otherwise might be provided to States for distribution under TEFAP.

For FY 2024, the Department anticipates purchasing the foods listed in the following table for distribution through TEFAP. The amounts of each item purchased will depend on the prices the Department must pay, as well as the quantity of each item requested by the States. Changes in agricultural market conditions may result in the availability of additional types of foods or the non-availability of one or more foods listed in the table.

FY 2024 USDA Foods Available List for The Emergency Food Assistance Program (TEFAP)

FRUITS:
- Apples, Braeburn, Fresh
- Apples, Empire, Fresh
- Apples, Fuji, Fresh
- Apples, Gala, Fresh
- Apples, Granny Smith, Fresh
- Apples, Red Delicious, Fresh
- Apples, Fresh
- Apple Juice, 100%, Unsweetened
- Apple Slices, Unsweetened, Frozen (IQF)
- Applesauce, Unsweetened, Canned (K)
- Applesauce, Unsweetened, Cups, Shelf-Stable
- Apricots, Halves, Extra Light Syrup, Canned
- Blueberries, Highbush, Frozen
- Cherry Apple Juice, 100%, Unsweetened
- Cranberry Apple Juice, 100%, Unsweetened
- Cranberries, Dried, Individual Portion
- Grape Juice, Concord, 100%, Unsweetened
- Grapefruit Juice, 100%, Unsweetened
- Fruit and Nut Mix, Dried
- Mixed Fruit, Extra Light Syrup, Canned
- Oranges, Fresh
- Orange Juice, 100%, Unsweetened
- Peaches, Freestone, Slices, Frozen
- Peaches, Sliced, Extra Light Syrup, Canned
- Pears, Bartlett, Fresh
- Pears, Bosc, Fresh
- Pears, D'Anjou, Fresh
- Pears, Fresh
- Pears, Extra Light Syrup, Canned (K)
- Plums, Pitted, Dried
- Raisins, Unsweetened, Individual Portion
- Raisins, Unsweetened
- Strawberries, Whole, Unsweetened, Frozen (IQF)

DAIRY:
- Cheese, American, Reduced Fat, Loaves, Refrigerated
- Cheese, Cheddar, Yellow, Shredded, Refrigerated
- Milk, 1%, Shelf-Stable UHT
- Milk, 1%, Individual Portion, Shelf-Stable UHT
- Milk 1% Fresh
- Milk, Skim, Fresh

VEGETABLES:

FY 2024 USDA Foods Available List for The Emergency Food Assistance Program (TEFAP)—Continued

- Beans, Green, Low-sodium, Canned (K)
- Beans, Green, No Salt Added, Frozen
- Carrots, Diced, No Salt Added, Frozen
- Carrots, Sliced, Low-sodium, Canned
- Corn, Whole Kernel, No Salt Added, Canned (K)
- Corn, Cream Style, Low sodium, Canned
- Mixed Vegetables, 7-Way Blend, Low-sodium, Canned
- Corn, Whole Kernel, No Salt Added, Frozen
- Mixed Produce Box, Fresh
- Mixed Vegetables, 7-Way Blend, Low-sodium, Canned
- Peas, Green, Low-sodium, Canned
- Peas, Green, No Salt Added, Frozen
- Potatoes, Dehydrated Flakes
- Potatoes, Round, Fresh
- Potatoes, Russet, Fresh
- Potatoes, Sliced, Low-sodium, Canned
- Pumpkin, No Salt Added, Canned
- Spaghetti Sauce, Low-sodium, Canned
- Spinach, Low-sodium, Canned
- Sweet Potatoes, Fresh
- Sweet Potatoes, Fresh
- Tomato Juice, 100%, Low-sodium
- Tomato Sauce, Low-sodium, Canned
- Tomato Sauce, Low-sodium, Canned (K) (H)
- Tomato Soup, Condensed, Low-sodium, Canned
- Tomatoes, Diced, No Salt Added, Canned
- Vegetable Soup, Condensed, Low-Sodium, Canned

LEGUMES:
- Beans, Black, Low-sodium, Canned
- Beans, Black-eyed Pea, Low-sodium, Canned
- Beans, Black-eyed Pea, Dry
- Beans, Garbanzo, Canned (K)
- Beans, Great Northern, Dry
- Beans, Kidney, Light Red, Low-sodium, Canned
- Beans, Kidney, Light Red, Dry
- Beans, Lima, Baby, Dry
- Beans, Pinto, Low-sodium, Canned
- Beans, Pinto, Dry
- Beans, Refried, Low-sodium, Canned
- Lentils, Dry
- Beans, Vegetarian, Low-sodium, Canned
- Peas, Green Split, Dry

PROTEIN FOODS:
- Alaska Pollock, Whole Grain Breaded Fish Sticks, Frozen
- Alaska Pollock, Fillets, Frozen
- Almonds, Natural, Whole, Shelled
- Atlantic Haddock, Fillet, Frozen
- Atlantic Ocean Perch, Fillet, Frozen
- Atlantic, Pollock, Fillet, Frozen
- Beef, Canned/Pouch
- Beef, Fine Ground, 85% Lean/15% Fat, Frozen
- Beef, Fine Ground, 85% Lean/15% Fat, Frozen, LFTB
- OPT, Frozen
- Beef Stew, Canned/Pouch
- Catfish, Fillets, Frozen
- Chicken, Boneless Breast, Frozen
- Chicken, Canned
- Chicken, Drumsticks, Frozen
- Chicken, Pouch

FY 2024 USDA FOODS AVAILABLE LIST FOR THE EMERGENCY FOOD ASSISTANCE PROGRAM (TEFAP)—Continued

Chicken, Split Breast, Frozen
Chicken, Whole, Frozen
Eggs, Fresh
Egg Mix, Dried
Peanut Butter, Smooth
Peanut Butter, Smooth (K)
Peanut Butter, Smooth, Individual Portion
Peanuts, Roasted, Unsalted
Pork, Canned/Pouch
Pork, Ham, Frozen
Pork, Chops, Boneless, Frozen
Salmon, Pink, Canned
Salmon, Pink, Canned (K)
Walnut, Pieces
GRAINS:
Bakery Mix, Low-fat
Cereal, Wheat Farina, Enriched
Crackers, Unsalted
Cornmeal, Yellow
Flour, All Purpose, Enriched, Bleached
Flour, White Whole Wheat (WG)
Grits, Corn, White
Grits, Corn, Yellow
Oats, Rolled, Quick Cooking (WG)
Pasta, Egg Noodles
Pasta, Macaroni, Enriched
Pasta, Macaroni (WG)
Pasta, Macaroni and Cheese
Pasta, Rotini (WG)
Pasta, Spaghetti, Enriched
Pasta, Spaghetti (WG)
Rice, Brown, Long-Grain, Parboiled (WG)
Rice, Medium Grain
Rice, Long Grain
Tortillas, Frozen (WG)
OILS:
Oil, Vegetable
OTHER:
Soup, Cream of Chicken, Condensed, Reduced Sodium
Soup, Cream of Mushroom, Condensed, Reduced Sodium

KEY:
H—Halal Certification Required.
K—Kosher Certification Required.
IQF—Individually Quick Frozen.
UHT—Ultra-High Temperature Pasteurization.
LFTB OTP—Lean Finely Textured Beef Optional.
WG—Whole Grain.

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2023–24667 Filed 11–7–23; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Directive Publication Notice

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice.

SUMMARY: The Forest Service (Forest Service or Agency), U.S. Department of Agriculture, provides direction to employees through issuances in its Directive System, comprised of the Forest Service Manual and Forest Service Handbooks. The Agency must provide public notice of and opportunity to comment on any directives that formulate standards, criteria, or guidelines applicable to Forest Service programs. Once per quarter, the Agency provides advance notice of proposed and interim directives that will be made available for public comment during the next three months; proposed and interim directives that were previously published for public comment but not yet finalized and issued; and notice of final directives issued in the last three months.

DATES: This notice identifies proposed and interim directives that will be published for public comment between October 1, 2023, and December 31, 2023; proposed and interim directives that were previously published for public comment but not yet finalized and issued; and final directives that have been issued since July 1, 2023.

ADDRESSES: Questions or comments may be submitted by email to the contact listed below.

FOR FURTHER INFORMATION CONTACT: JoLynn Anderson, 971–313–1718 or *jolynn.anderson@usda.gov.* Individuals who use telecommunications devices for the hearing impaired may call the Federal Relay Service at 800–877–8339 24 hours a day, every day of the year, including holidays. You may register to receive email alerts regarding Forest Service directives at *https://www.fs.usda.gov/about-agency/regulations-policies.*

SUPPLEMENTARY INFORMATION:

Proposed and Interim Directives

Consistent with 16 U.S.C. 1612(a) and 36 CFR part 216, the Forest Service publishes for public comment Agency directives that formulate standards, criteria, and guidelines applicable to Forest Service programs. Agency procedures for providing public notice and opportunity to comment are specified in Forest Service Handbook (FSH) 1109.12, Chapter 30, Providing Public Notice and Opportunity to Comment on Directives.

The following proposed directives are planned for publication for public comment from October 1, 2023, to December 31, 2023:

1. Forest Service Manual (FSM) 2000, National Forest Resource Management, Chapter 40, National Forest System Monitoring (published as planned for publication for public comment on August 9, 2023 (88 FR 53859)).

2. FSM 2300, Recreation, Wilderness, and Related Resource Management, Chapter 50, section 55, Climbing Management (published as planned for publication for public comment on August 9, 2023 (88 FR 53859)).

3. FSM 2100, Environmental Management, Chapter 80, Mitigation of Adverse Impacts.

4. FSH 2709.11, Special Uses Handbook, Chapter 70, Renewable Energy (currently entitled Wind Energy Uses).

The following proposed directives have been published for public comment but have not yet been finalized:

1. FSM 2200, Rangeland Management, Chapters Zero Code; 2210, Rangeland Management Planning; 2220, Management of Rangelands (Reserved); 2230, Grazing Permit System; 2240, Rangeland Improvements; 2250, Rangeland Management Cooperation; and 2270, Information Management and Reports; FSH 2209.13, Grazing Permit Administration Handbook, Chapters 10, Term Grazing Permits; 20, Grazing Agreements; 40, Livestock Use Permits; 50, Tribal Treaty Authorizations and Special Use Permits; and 90, Rangeland Management Decision Making; and FSH 2209.16, Allotment Management Handbook, Chapter 10, Allotment Management and Administration.

2. FSM 3800, Landscape Scale Restoration Program.

3. FSH 2409.12, Timber Cruising Handbook, Chapters 30, Cruising Systems; 40, Cruise Planning, Data Recording, and Cruise Reporting; 60, Quality Control; and 70, Designating Timber for Cutting; FSH 2409.15, Timber Sale Administration Handbook, Chapters 20, Measuring and Accounting for Included Timber; 40, Rates and Payments; and 60, Operations and Other Provisions.

4. FSH 5509.11, Title Claims, Sales, and Grants Handbook, Chapter 10, Title Claims and Encroachments.

Final Directives That Have Been Issued Since July 1, 2023

No final directives have been issued since July 1, 2023.

JoLynn Anderson,

Branch Lead, Directives, Information Collections and Government Clearance, Policy Office, National Forest System.

[FR Doc. 2023–24697 Filed 11–7–23; 8:45 am]

BILLING CODE 3411–15–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Information Collection Request 30-Day Notice

AGENCY: Chemical Safety and Hazard Investigation Board (CSB).

ACTION: 30-Day notice of submission of information collection request (ICR) approval and request for comments.

SUMMARY: The proposed information collection request (ICR) renewal described below will be submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995 (PRA). The Chemical Safety Board (CSB) is soliciting public comments on this proposed collection renewal. The CSB on its own made additional changes to the survey instructions and survey questions. Additionally, the agency reviewed time considerations for completing the survey and increased the time to complete the survey. Previously, the CSB included information regarding interviews. This information collection request is only for the survey; the information regarding the interviews has been eliminated because the interviews do not fall under the PRA. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: Comments should be sent no later than 5 p.m. EST on Friday, December 8, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions within 30 days of publication of this notice: OMB, Office of Information and Regulatory Affairs, Attention: Chemical Safety Board Desk Officer, Fax Number: (202) 395–5806 *OR,* Email: *OIRA_submission@omb.eop.gov.*

Additionally, written comments and recommendations for the proposed information collection may be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection request, select ''Currently under 30-day Review—Open for Public Comments'' or use the search function.

Requests for information, including copies of the information collection proposed and supporting documentation, should be directed to: Chris Lyon, Acting General Counsel, U.S. Chemical Safety and Hazard Investigation Board, at *reactives@csb.gov.*

FOR FURTHER INFORMATION CONTACT: Chris Lyon, Acting General Counsel, U.S. Chemical Safety and Hazard Investigation Board, 1750 Pennsylvania Ave. NW, Suite 910, Washington, DC 20006; reactives@*csb.gov;* or 202–261–7600.

SUPPLEMENTARY INFORMATION:

Title: CSB Reactive Hazard Study Survey of Industry Practices.

Type of Request: Approval.

Abstract: The enabling statute of the Chemical Safety and Hazard Investigation Board (CSB) provides that the CSB is ''authorized to conduct research and studies with respect to the potential for accidental releases, whether or not an accidental release has occurred, where there is evidence which indicates the presence of a potential hazard or hazards.'' 42 U.S.C. 7412(r)(6)(F).

In August 2000, the CSB initiated a review of reactive hazards nationwide. The purpose of the investigation was to develop recommendations to reduce the number and severity of such incidents. The CSB published Hazard Investigation: Improving Reactive Hazard Management on September 17, 2002. The CSB issued a total of 24 recommendations to 15 organizations. One recommendation and one superseded recommendation remain.

This information collection request will assist the CSB in updating its 2002 study, ''Hazard Investigation: Improving Reactive Hazard Management.'' On behalf of the CSB, the Federal Research Division (FRD) within the Library of Congress is conducting the study to compile current research, data, and company safety policies concerning reactive chemical incidents.

For this study, FRD on behalf of CSB intends on collecting survey data from 24 randomly selected small/medium and large companies that use reactive chemicals.

Type of Respondents: All the respondents will be private sector businesses that use reactive chemicals that voluntarily submit to the survey.

Estimate Annual Number of Respondents: 24. This represents the maximum number of respondents.

Frequency of Use: Once. This survey is part of a study.

Small Businesses or Organizations Affected: None. Although the CSB is contacting small businesses, this survey is voluntary. Additionally, the CSB anticipates a total of 15 companies will respond.

Estimated Number of Annual Responses: 24. This represents the maximum number of possible responses.

Estimated Average Burden Hours per Response: 6 hours. The survey should take a representative from each of the companies randomly selected four to eight hours to complete. The estimated financial burden for one process safety manager to take this survey is $375.57. For 15 surveys (the anticipated amount of responses), the total cost of process safety managers' time is estimated to be $5,633.55.[1]

Estimated Total Annual Burden Hours: 90 hours. This represents the total average burden (6 hours per 15 responses).

Need for and Use of Information: This research is vital because safely conducting chemical reactions is essential for the chemical manufacturing industry. Chemical reactive hazards can rapidly release large quantities of heat, energy, and gaseous byproducts. Uncontrolled reactions have led to serious explosions, fires, and toxic emissions. The impacts may be severe in terms of death and injury to people, damage to physical property, and effects on the environment and surrounding communities. Since the publication of the 2002 report, incidents caused by uncontrolled chemical reactions have persisted. This fact suggests the need to continue to evaluate existing standards and improve the management of reactive hazards in response to changes within the chemical manufacturing industry over the past two decades.

Researchers will use quantitative and qualitative mixed methods to analyze the collected industry information. The analysis will identify trends and present insights which will enhance the CSB's capacity to respond to future reactive chemical incidents and to inform industry stakeholders of the best practices in process safety protocols.

Comment is Invited: Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have

[1] The burden is calculated by taking the 6-hour time burden for a process safety manager multiplied by the number of surveys; an average Process Safety Manager makes $100,154 per year as of September 15, 2022, which in terms of hourly compensation is $48.15. $48.15 hourly pay * 1.3 (benefits) * 6 hours to complete * 15 surveys = 5,633.55. See ''Process Safety Manager Salaries,'' Glassdoor, Updated September 15, 2022, *https://www.glassdoor.com/Salaries/process-safety-manager-salary-SRCH_KO0,22.htm.*

practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the 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 the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. To view the draft protocol, please see: *https://www.csb.gov/assets/1/6/csb_survey_draft_2023.11.02.pdf.*

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. As of the time of this notice, the CSB has not received any comments. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

Dated: November 3, 2023.

Tamara Qureshi,

Assistant General Counsel, Chemical Safety and Hazard Investigation Board.

[FR Doc. 2023–24693 Filed 11–7–23; 8:45 am]

BILLING CODE 6350–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Request for Nominations of Members To Serve on the National Advisory Committee on Racial, Ethnic, and Other Populations

AGENCY: Census Bureau, Commerce.

ACTION: Notice of request for nominations.

SUMMARY: The Director of the Census Bureau (Director) is seeking nominations for the National Advisory Committee on Racial, Ethnic and Other Populations (NAC or Committee). The purpose of the NAC is to provide advice to the Director on the full range of economic, housing, demographic, socioeconomic, linguistic, technological, methodological, geographic, behaviorial and operational variables affecting the cost, accuracy and implementation of Census Bureau programs and surveys, including the decennial census. The Director has determined that the work of the NAC is in the public interest and relevant to the duties of the Census Bureau. Therefore, the Director is seeking nominations to fill vacancies on the NAC. Additional information concerning the NAC can be found by visiting the NAC's website at: *https://www.census.gov/about/cac/nac.html.*

DATES: Nominations must be received on or before Wednesday, January 10, 2024. Nominations must contain a completed resumé. The Census Bureau will retain nominations received after the deadline for consideration should additional vacancies occur.

ADDRESSES: Please submit nominations via email to the address listed below, *census.national.advisory.committee@census.gov* (subject line 2024 NAC Nominations'').

FOR FURTHER INFORMATION CONTACT: Shana Banks, Chief, Advisory Committee Brach, Office of Program, Performance and Stakeholder Integration (PPSI), Census Bureau, by telephone at 301–763–3815 or by email at *Shana.J.Banks@census.gov.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., eastern standard time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Federal Advisory Committee Act, as amended (FACA), 5 United States Code (U.S.C.) app, the Director of the Census Bureau is seeking nominations for the National Advisory Committee on Racial, Ethnic, and Other Populations (NAC). The NAC will operate under the provisions of FACA and will report to the Director of the Census Bureau.

The Census Bureau's National Advisory Committee on Racial, Ethnic, and Other Populations will advise the Director of the Census Bureau on the full range of Census Bureau programs and activities. The Committee will provide race, ethnic, and other population expertise from the following disciplines: economic, housing, demographic, socioeconomic, linguistic, technological, methodological, geographic, and behavioral and operational variables affecting the cost, accuracy, and implementation of Census Bureau programs and surveys, including the decennial census.

Objectives and Duties

1. The NAC advises the Director of the Census Bureau (the Director) on the full range of economic, housing, demographic, socioeconomic, linguistic, technological, methodological, geographic, behavioral, and operational variables affecting the cost, accuracy, and implementation of Census Bureau programs and surveys, including the decennial census.

2. The NAC advises the Census Bureau on the identification of new strategies for improved census operations, and survey and data collection methods, including identifying cost efficient ways to increase census participation.

3. The NAC addresses census policies, research and methodology, tests, operations, communications/messaging, and other activities to ascertain needs and best practices to improve censuses, surveys, operations, and programs.

4. The NAC reviews and provides formal recommendations and feedback on working papers, reports, and other documents related to the design and implementation of Census Bureau programs and surveys.

5. The NAC utilizes Regional Office participation to identify regional, local, Tribal, and grassroots issues, and trends and perspectives related to Census Bureau surveys and programs.

6. The NAC, in providing insight, perspectives, and expertise on the full spectrum of Census Bureau surveys and programs to assist the Census Bureau in: developing appropriate research and methodologies, operations, communications, and strategies to reduce program/survey costs; improving coverage and operational efficiency; improving the quality of data collected; protecting the public's and business units' privacy; enhancing public participation and awareness of Census Bureau programs and surveys; improving the dissemination of data products; and the use of administrative records and third party data in the decennial census.

7. In providing insight, perspectives, and expertise on the full spectrum of Census Bureau surveys and programs, the NAC examines such areas as hidden households, language barriers, students and youth, aging populations, American Indian and Alaska Native tribal considerations, new immigrant populations, populations affected by natural disasters, highly mobile and migrant populations, complex households, poverty, race/ethnic distribution, privacy and confidentiality, rural populations and businesses, individuals and households with limited access to information and communications technologies, the dynamic nature of new businesses, minority ownership of businesses, as well as other concerns impacting Census Bureau survey design and implementation.

8. The NAC functions solely as an advisory body and shall fully comply with the provisions of FACA.

Membership

1. The NAC consists of up to 32 members who serve at the discretion of the Director. The Census Bureau is seeking qualified candidates to be considered for appointment.

2. The NAC aims to have a balanced representation among its members, considering such factors as geography, technical expertise, community involvement, and knowledge of census programs and/or activities. The diverse membership of the Committee assures expertise and perspectives reflecting the full breadth of the Committee's responsibilities, and, where possible, the Census Bureau will also consider the diversity of the United States population, including sex, age, race, ethnicity, and other factors as applicable.

3. The NAC aims to include members from diverse populations (including race and ethnic populations); national, state, local and tribal interest organizations serving hard-to-count populations; research community-based organizations; academia; business interests, organized labor; marketing and media; and professional associations.

4. Members will be selected from the public and private sectors. Members will as Special Government Employees (SGEs) as defined in title 18 of United States Code, section 202(a).

5. SGEs are appointed for their personal expertise and may not use alternates to fulfill Committee functions. Members will be individually advised of the capacity in which they will serve through their appointment letters.

6. Membership is open to persons who are not seated on other Census Bureau stakeholder entities (*i.e.,* State Data Centers, Census Information Centers, Federal State Cooperative on Populations Estimates Program, other Census Advisory Committees, etc.). People who have already served one full-term on a Census Bureau Advisory Committee may not serve on any other Census Bureau Advisory Committee for three years from the termination of previous service. No employee of the federal government can serve as a member of the NAC.

7. Members will serve for a three-year term. Members may be evaluated at the conclusion of their first term with the prospect of renewal, pending Committee needs. Active attendance and participation in meetings and activities (*e.g.,* conference calls and assignments) will be factors considered when determining term renewal or membership continuance. Members may be appointed for a second three-year term at the discretion of the Director.

8. Members will be selected on a standardized basis, in accordance with applicable Department of Commerce guidance.

Miscellaneous

1. Members of the NAC shall not be compensated for their participation, but will, upon request, be allowed travel and per diem expenses as authorized by 5 U.S.C. 5703.

2. The NAC meets twice a year, budget and environment conditions permitting, but additional meetings may be held as deemed necessary by the Census Bureau Director or Designated Federal Officer. All NAC meetings are open to the public in accordance with the FACA.

Nomination Process

1. Nominations should satisfy the requirements described in the Membership section above.

2. Individuals, groups, and/or organizations may submit nominations on behalf of candidates. A summary of the candidate's qualifications (resumé or curriculum vitae) must be included along with the nomination letter. Nominees must be able to actively participate in the tasks of the committee, including, but not limited to, regular meeting attendance, committee meeting discussant responsibilities, review of materials, as well as participation in conference calls, webinars, working groups, and/or special committee activities.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks diverse NAC membership.

Robert L. Santos, Director, Census Bureau, approved the publication of this notice in the **Federal Register**.

Dated: November 2, 2023.

Shannon Wink,

Program Analyst, Policy Coordination Office, U.S. Census Bureau.

[FR Doc. 2023–24662 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Direct Investment Surveys: BE–605, Quarterly Survey of Foreign Direct Investment in the United States—Transactions of U.S. Affiliate With Foreign Parent

AGENCY: Bureau of Economic Analysis, Department of 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: Written comments must be submitted on or before January 8, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Jessica Hanson, Chief, Direct Investment Division, Bureau of Economic Analysis, U.S. Department of Commerce, by email to *Jessica.Hanson@bea.gov* and *PRAcomments@doc.gov.* Please reference OMB Control Number 0608–0009 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 Jessica Hanson, Chief, Direct Investment Division, Bureau of Economic Analysis, U.S. Department of Commerce; via phone at (301) 278–9595; or via email at *Jessica.Hanson@bea.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Quarterly Survey of Foreign Direct Investment in the United States—Transactions of U.S. Affiliate with Foreign Parent (Form BE–605) obtains quarterly data on transactions and positions between foreign-owned U.S. business enterprises and their ''affiliated foreign groups'' (*i.e.,* their foreign parents and foreign affiliates of their foreign parents). The survey is a sample survey that covers all U.S. affiliates

above a size-exemption level. The sample data are used to derive universe estimates of direct investment transactions, positions, and income in nonbenchmark years from similar data reported in the BE–12, Benchmark Survey of Foreign Direct Investment in the United States, which is conducted every five years. The data collected through the BE–605 survey are essential for the preparation of the U.S. international transactions, national income and product, and input-output accounts and the net international investment position of the United States. The data are needed to measure the size and economic significance of foreign direct investment in the United States, measure changes in such investment, and assess its impact on the U.S. economy. The Bureau of Economic Analysis (BEA) is not proposing any changes to the BE–605 survey.

II. Method of Collection

Notice of specific reporting requirements, including who is to report, the information to be reported, the manner of reporting, and the time and place of filing reports, will be mailed to potential respondents each quarter. Reports are due 30 days after the close of each calendar or fiscal quarter, or 45 days if the report is for the final quarter of the respondent's financial reporting year. Reports are required from every U.S. business enterprise in which a foreign entity owns, directly and/or indirectly, 10 percent or more of the voting securities of the U.S. business enterprise if it is incorporated, or an equivalent interest if it is unincorporated, at any time during the quarter, and that meets the additional conditions detailed in Form BE–605. Certain private funds are exempt from reporting. Entities required to report will be contacted individually by BEA. Entities not contacted by BEA have no reporting responsibilities.

Potential respondents include those U.S. business enterprises that were required to report on the BE–12, Benchmark Survey of Foreign Direct Investment in the United States—2017, along with those U.S. business enterprises that subsequently have become at least partly foreign owned. BEA offers electronic filing through its eFile system (*www.bea.gov/efile*) for use in reporting on the BE–605 survey forms. In addition, BEA posts its survey forms and reporting instructions on its website (*www.bea.gov/fdi*).

III. Data

OMB Control Number: 0608–0009.

Form Number: BE–605.

Type of Review: Regular submission, reinstatement without change.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 6,500 per quarter, 26,000 annually.

Estimated Time per Response: 1 hour is the average but may vary considerably among respondents because of differences in company structure and complexity.

Estimated Total Annual Burden Hours: 26,000.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended by Pub. L. 98–573 and Pub. L. 101–533).

IV. Request for Comments

We are soliciting public comments to permit the Bureau of Economic Analysis 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. 2023–24618 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

[Docket Number 231102–0260]

Federal Economic Statistics Advisory Committee Meeting

AGENCY: Bureau of Economic Analysis, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Bureau of Economic Analysis (BEA) is giving notice of a meeting of the Federal Economic Statistics Advisory Committee (FESAC or the Committee). The Committee advises the Under Secretary for Economic Affairs, the Directors of the Bureau of Economic Analysis and the Census Bureau, and the Commissioner of the U.S. Department of Labor's Bureau of Labor Statistics (BLS) on statistical methodology and other technical matters related to the collection, tabulation, and analysis of federal economic statistics. An agenda will be accessible prior to the meeting at *https://apps.bea.gov/fesac/.*

DATES: December 8, 2023. The meeting begins at 10 a.m. and adjourns at 3:30 p.m. (ET).

ADDRESSES: This meeting will be a hybrid event. Committee members and presenters will have the option to join the meeting in person or via video conference technology. All outside attendees will be invited to attend via video conference technology only. The meeting is open to the public via video conference technology. Contact Gianna Marrone at (301) 278–9282 or *gianna.marrone@bea.gov* by December 1, 2023, to RSVP. The Advisory Committee website will maintain the most current information on the meeting agenda, schedule, and location. These items may be updated without further notice in the **Federal Register**. Information about how to access the meeting and presentations will be posted 24 hours prior to the meeting on *https://apps.bea.gov/fesac/.*

FOR FURTHER INFORMATION CONTACT: Gianna Marrone, Program Analyst, U.S. Department of Commerce, Bureau of Economic Analysis, 4600 Silver Hill Road (BE–64), Suitland, MD 20746; phone (301) 278–9282; email *gianna.marrone@bea.gov.*

SUPPLEMENTARY INFORMATION: FESAC members are appointed by the Secretary of Commerce. The Committee advises the Under Secretary for Economic Affairs, BEA and Census Bureau Directors, and the Commissioner of the Department of Labor's BLS on statistical methodology and other technical

matters related to the collection, tabulation, and analysis of federal economic statistics. The Committee is established in accordance with the Federal Advisory Committee Act (5 U.S.C. app. 2).

The Committee aims to have a balanced representation among its members, considering such factors as geography, age, sex, race, ethnicity, technical expertise, community involvement, and knowledge of programs and/or activities related to FESAC. Individual members are selected based on their expertise in or representation of specific areas as needed by FESAC.

This meeting is open to the public and is accessible to people with disabilities. Requests for foreign language interpretation, other auxiliary aids, or persons with extensive questions or statements should be directed to Gianna Marrone at *gianna.marrone@bea.gov* by December 1, 2023.

Authority: Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., app.

Dated: November 2, 2023.

Sabrina Montes,

Designated Federal Officer, Bureau of Economic Analysis.

[FR Doc. 2023–24617 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–844]

Steel Concrete Reinforcing Bar From Mexico: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that certain producers and/or subject to this administrative review sold steel concrete reinforcing bar (rebar) from Mexico at less than normal value during the period of review (POR) November 1, 2021, through October 31, 2022. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 8, 2023.

FOR FURTHER INFORMATION CONTACT: Kyle Clahane, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5449.

SUPPLEMENTARY INFORMATION:

Background

On November 6, 2014, Commerce published in the **Federal Register** the antidumping duty order on rebar from Mexico.[1] On November 1, 2022, Commerce published in the **Federal Register** a notice of opportunity to request administrative reviews of the *Order*.[2] On January 3, 2023, based on timely requests for review, in accordance with section 751(a)(1) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the *Order* covering 20 companies.[3] On January 3, 2023, we selected Deacero Group [4] and Grupo Acerero S.A. de C.V. (Acerero) for individual examination as the mandatory respondents in this administrative review.[5] Pursuant to section 751(a)(3)(A) of the Act, Commerce extended the deadline for the preliminary results until November 3, 2023.[6]

For a complete description of the events that followed the initiation of the review, *see* the Preliminary Decision Memorandum.[7] A list of topics included in the Preliminary Decision Memorandum is included in the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The merchandise subject to the *Order* is steel concrete reinforcing bar from Mexico. The rebar subject to the *Order* is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7213.10.0000, 7214.20.0000, 7228.30.8010, 7215.90.1000, 7215.90.5000, 7221.00.0017, 7221.00.0018, 7221.00.0030, 7221.00.0045, 7222.11.0001, 7222.11.0057, 7222.11.0059, 7222.30.0001, 7227.20.0080, 7227.90.6085, 7228.20.1000, and 7228.60.6000. While HTSUS subheadings are provided for convenience and Customs purposes, the written description of the scope of the *Order* is dispositive. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. Constructed export price was calculated in accordance with section 772 of the Act. Normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our preliminary results, *see* the Preliminary Decision Memorandum.

Rate for Non-Selected Companies

For the rate for companies not selected for individual examination in an administrative review, generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a less-than-fair-value (LTFV) investigation. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.'' In this administrative review, we calculated weighted-average dumping margins for Deacero Group and Acerero that are not zero, *de minimis,* or based entirely on total facts available. For the respondents that were not selected for individual examination in this administrative review, we have assigned to them the weighted-average dumping margins calculated for Deacero Group and Acerero, consistent with the

[1] *See Steel Concrete Reinforcing Bar from Mexico: Antidumping Duty Order,* 79 FR 65925 (November 6, 2014) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 87 FR 65750 (November 1, 2022).

[3] *See Initiation of Antidumping Duty and Countervailing Duty Administrative Reviews,* 88 FR 50 (January 3, 2023).

[4] Deacero Group consists of Deacero S.A.P.I. de C.V. (Deacero); and I.N.G.E.T.E.K.N.O.S. Estructurales, S.A. de C.V.. *See Steel Concrete Reinforcing Bar from Mexico: Final Results of Antidumping Duty Administrative Review; 2020–2021,* 88 FR 37849 (June 9, 2023), and accompanying Issues and Decision Memorandum (IDM) at Comment 4.

[5] *See* Memoranda, ''Respondent Selection,'' dated February 17, 2023; and ''Additional Respondent Selection,'' dated February 22, 2023.

[6] *See* Memorandum, ''Second Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated October 4, 2023.

[7] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Steel Concrete Reinforcing Bar from Mexico; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

guidance in section 735(c)(5)(B) of the Act.[8]

Preliminary Results of Review

We preliminarily determine the following estimated weighted-average dumping margins exist for the period November 1, 2021, through October 31, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
Deacero S.A.P.I. de C.V./I.N.G.E.T.E.K.N.O.S. Estructurales, S.A. de C.V	2.27
Grupo Acerero S.A. de C.V	5.49
Grupo Simec S.A.B. de C.V./Aceros Especiales Simec Tlaxcala, S.A. de C.V./Compania Siderurgica del Pacifico S.A. de C.V./ Fundiciones de Acero Estructurales, S.A. de C.V./Grupo Chant S.A.P.I. de C.V./Operadora de Perfiles Sigosa, S.A. de C.V./ Orge S.A. de C.V./Perfiles Comerciales Sigosa, S.A. de C.V./RRLC S.A.P.I. de C.V./Siderúrgicos Noroeste, S.A. de C.V./ Siderurgica del Occidente y Pacifico S.A. de C.V./Simec International, S.A. de C.V./Simec International 6 S.A. de C.V./Simec International 7 S.A. de C.V./Simec International 9 S.A. de C.V.)	2.88
Gerdau Corsa, S.A.P.I. de C.V	2.88
Sidertul S.A. de C.V	2.88

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to interested parties within five days after the date of publication of this notice in accordance with 19 CFR 351.224(b).

Interested parties will be notified of the timeline for the submission of such case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.[9] Parties who submit case or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[10] Executive summaries should be limited to five pages total, including footnotes.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via Commerce's electric records system, ACCESS, within 30 days of the date of publication of this notice in the **Federal Register**.[11] Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.

All submissions to Commerce should be filed using ACCESS.[12] An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the date that the document is due. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[13]

Final Results of Review

Unless extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in the case and rebuttal briefs, within 120 days of publication of these preliminary results in the **Federal Register**.[14]

Assessment Rates

Upon issuance of the final results of this administrative review, pursuant to section 751(a)(2)(A) of the Act, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise.

For individually examined respondents whose weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent), we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). If the respondent has not reported entered values, we will calculate a per-unit assessment rate for each importer by dividing the total amount of dumping calculated for the examined sales made to that importer by the total quantity associated with those sales. To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values. Where either a respondent's weighted average dumping margin is zero or *de minimis,* or an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we intend to instruct CBP to liquidate appropriate entries without regard to antidumping duties.[15]

For entries of subject merchandise during the POR produced by each individually examined respondent for which the producer did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate (20.58 percent) if there is no rate for the intermediate company(ies) involved in the transaction.[16]

For those companies which were not individually examined, we will instruct CBP to assess antidumping duties at an

[8] *See* Preliminary Decision Memorandum at the section, ''Companies Not Selected For Individual Examination''; *see also* Memorandum, ''Calculation of the Rate for Respondents Not Selected for Individual Examination,'' dated concurrently with this notice; and *Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010).

[9] *See* 19 CFR 351.309(d).

[10] *See* 19 CFR 351.309(c)(2) and (d)(2).

[11] *See* 19 CFR 351.310(c).

[12] *See* 19 CFR 351.303.

[13] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[14] *See* section 751(a)(3)(A) of the Act; *see also* 19 CFR 351.213(h).

[15] *See* 19 CFR 351.106(c)(2); *see also Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[16] *See Order,* 73 FR at 45405; *see also Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

ad valorem rate equal to the weighted-average dumping margin determined for the non-examined companies in the final results of this review.

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review where applicable. Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for each specific company listed above will be that established in the final results of this administrative review, except if the rate is less than 0.50 percent, and therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or in the investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 20.58 percent, the rate established in the investigation of this proceeding.[17] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, 19 CFR 351.213(h)(2), and 19 CFR 351.221(b)(4).

Dated: November 1, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2023–24666 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–DS–P

[17] *See Steel Concrete Reinforcing Bar from Mexico: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 79 FR 54967 (September 15, 2014).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD500]

Fisheries of the Gulf of Mexico and South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 79 Pre-Assessment Webinar for Gulf of Mexico and South Atlantic Mutton Snapper.

SUMMARY: The SEDAR 79 assessment process of Gulf of Mexico and South Atlantic mutton snapper will consist of a Data Workshop, and a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 79 Pre-Assessment webinar will be held November 28, 2023, from 1 p.m. to 3 p.m., Eastern Time. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the webinar are as follows: Panelists will review the data sets being considered for the assessment and discuss initial assessment modeling issues.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will

be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 3, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–24686 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD499]

Caribbean Fishery Management Council; Public Meeting

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

ACTION: Notice of a public virtual meeting.

SUMMARY: The Caribbean Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) will hold a public virtual meeting to address the items contained in the tentative agenda included in the **SUPPLEMENTARY INFORMATION.**

DATES: The SSC public virtual meeting will be held on November 28, 2023, from 9 a.m. to 5 p.m., Atlantic Standard Time.

ADDRESSES: You may join the SSC public virtual meeting (via Zoom) from a computer, tablet, or smartphone by entering the following address: *https://us02web.zoom.us/j/81086075177?pwd=TlBLb0NjWmZaR2h0b2NEbmpOTWtiQT09.*

Meeting ID: 810 8607 5177
Passcode: 546850
One tap mobile
+17193594580,,
81086075177#,,,,*546850# US
+12532050468,,
81086075177#,,,,*546850# US
Dial by your location
+1 301 715 8592 US (Washington, DC)
+1 305 224 1968 USs
+1 309 205 3325 US
+1 646 558 8656 (New York)
+1 669 900 9128 US (San Jose)
Meeting ID: 810 8607 5177
Passcode: 546850

Find your local number: https://us02web.zoom.us/u/kQvrOfR9i.

In case of problems with ZOOM, please join the meeting via GoToMeeting by entering the following address: *https://meet.goto.com/768055309.*

You can also dial in using your phone.

Access Code: 768–055–309
United States: +1 (571) 757–317–3122

Join from a video-conferencing room or system.

Meeting ID: 768–055–309
Dial in or type: 67.217.95.2 or *inroomlink.goto.com*
Or dial directly: 768055309@67.217.95.2 or 67.217.95.2##768055309

Get the app now and be ready when your first meeting starts: *https://meet.goto.com/install.*

FOR FURTHER INFORMATION CONTACT: Graciela García-Moliner, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918–1903, telephone: (787) 766–5926.

SUPPLEMENTARY INFORMATION: The following items included in the tentative agenda will be discussed:

November 28, 2023

9 a.m.–9:30 a.m.

—Roll Call
—Approval of Agenda
—Approval of Minutes

9:30 a.m.–12:30 p.m.

—SEDAR 80 USVI Queen Triggerfish—Adyan Rios, SEFSC Caribbean Fisheries Branch, and Kyle Shertzer, SEFSC Atlantic Fisheries Branch
—Recommendations to CFMC on SEDAR 80

12:30 p.m.–1:30 p.m.

—Lunch Break

1:30 p.m.–3 p.m.

—Finalize SSC Recommendations to CFMC on SEDAR 80
—SSC Participation for SEADR 84 (yellowtail snapper for Puerto Rico and St. Thomas/St. John and stoplight parrotfish for St. Croix)

3 p.m.–5 p.m.

—Other Business
—Next Meeting
—Adjourn

The order of business may be adjusted as necessary to accommodate the completion of agenda items. The meeting will begin on November 28, 2023, at 9 a.m. AST, and will end on November 28, 2023, at 5 p.m., AST. Other than the start time, interested parties should be aware that discussions may start earlier or later than indicated, at the discretion of the Chair. In addition, the meeting may be completed prior to the date established in this notice.

Special Accommodations

For any additional information on this public virtual meeting, please contact Dr. Graciela García-Moliner, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918–1903, telephone: (787) 403–8337.

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

Dated: November 3, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–24687 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD496]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of web conference.

SUMMARY: The North Pacific Fishery Management Council (Council) Crab Plan Team will hold a meeting.

DATES: The meeting will be held on Friday, December 1, 2023, from 9 a.m. to 1 p.m., AK time.

ADDRESSES: The meeting will be a web conference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/3023.* Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: Sarah Rheinsmith, Council staff; phone: (907) 271–2809; email: *sarah.rheinsmith@noaa.gov.* For technical support, please contact our admin Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Friday, December 1, 2023

The Crab Plan Team will meet to discuss research priorities. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/3023* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone, or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/3023.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/3023.*

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

Dated: November 2, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–24640 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD507]

Marine Mammals; File No. 26667

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

ACTION: Notice; receipt of application for permit amendment.

SUMMARY: Notice is hereby given that North Slope Borough Department of Wildlife Management (Taqulik Hepa, Responsible Party), P.O. Box 69, Barrow, AK 99723, has applied for an amendment to scientific research Permit No. 26667–01.

DATES: Written comments must be received on or before December 8, 2023.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 26667 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 26667 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Shasta McClenahan, Ph.D., (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject amendment to Permit No. 26667 is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

Permit No. 26667, issued on September 20, 2022 (87 FR 61573, October 12, 2022), authorizes the permit holder to collect, receive, import, and export biological samples from Alaskan pinnipeds and cetaceans annually for scientific research, including the creation and maintenance of cell lines. The permit holder is requesting the permit be amended to add a new objective for research on parts from cetaceans outside of Alaska. This includes the annual import, export, and receipt of parts from the Eastern Canada-West Greenland stock of bowhead whales (N = 300 animals) and parts from all other cetacean species (N = 1,500 animals).

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: November 1, 2023.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023–24676 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD451]

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 88 Red Tide Topical Working Group Scoping Webinar for Gulf of Mexico Red Grouper.

SUMMARY: The SEDAR 88 assessment of Gulf of Mexico red grouper will consist of a series of webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 88 Red Tide Topical Working Group Scoping Webinar will be held November 27, 2023, from 10 a.m. to 12 p.m., Eastern.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data

Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the webinar are as follows:

Participants will discuss what red tide data may be available for use in the assessment of Gulf of Mexico red grouper.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 10 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 2, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–24641 Filed 11–7–23; 8:45 am]

BILLING CODE 3510–22–P

COMMISSION OF FINE ARTS

Notice of Meeting

Per 45 CFR 2102.3, the next meeting of the U.S. Commission of Fine Arts is scheduled for November 16, 2023, at 9 a.m. and will be held via online videoconference. Items of discussion may include buildings, infrastructure, parks, memorials, and public art.

Draft agendas, the link to register for the online public meeting, and additional information regarding the Commission are available on our website: *www.cfa.gov.* Inquiries regarding the agenda, as well as any public testimony, should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing *cfastaff@cfa.gov;* or by calling 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated November 3, 2023 in Washington, DC.

Susan M. Raposa,

Technical Information Specialist.

[FR Doc. 2023–24671 Filed 11–7–23; 8:45 am]

BILLING CODE 6330–01–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2023–0039; OMB Control Number 0704–0341; Req. No. DARS–2024–00006–FR]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Part 239, Acquisition of Information Technology

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed revision and extension of an approved information collection requirement.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, DoD announces the proposed revision and extension of a public information collection requirement and seeks public comment on the provisions thereof. DoD invites comments on: whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of DoD'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. The Office of Management and Budget (OMB) has approved this information collection for use under OMB Control Number 0704–0341 through March 31, 2024. DoD proposes that OMB approve an extension of the information collection requirement, to expire three years after the approval date.

DATES: DoD will consider all comments received by January 8, 2024.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0341, using either of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments.

Email: osd.dfars@mail.mil. Include OMB Control Number 0704–0341 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Heather Kitchens, 571–296–7152.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 239, Acquisition of Information Technology, and associated clause at DFARS 252.239–7000; OMB Control Number 0704–0341.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Reporting Frequency: On occasion.

Number of Respondents: 1,880.

Responses per Respondent: 8.6, approximately.

Annual Responses: 16,172.

Average Burden per Response: 0.5 hour.

Annual Burden Hours: 8,086.

Needs and Uses: This requirement provides for the collection of information from contractors regarding security of information technology. Contracting officers and other DoD personnel use the information to ensure that information technology is

protected. The clause at DFARS 252.239–7000, Protection Against Compromising Emanations, requires that the contractor provide, upon request of the contracting officer, documentation that information technology used or provided under the contract meets appropriate information assurance requirements.

The requirement at DFARS 239.7408, which requires the contracting officer to obtain a detailed special construction proposal from a common carrier that submits a proposal or quotation that has special construction requirements related to the performance of basic telecommunications services, is being removed from this collection. Approximately three offerors are required to submit a special construction proposal each year, which does not require OMB approval under the Paperwork Reduction Act because it does not meet the threshold of ten or more members of the public being affected within any 12-month period.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

[FR Doc. 2023–24690 Filed 11–7–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2023–0041; OMB Control Number 0704–0390; Req. No. DARS–2024–00008–FR]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement (DFARS) Part 229, Taxes

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. DoD invites comments on: whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of DoD'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 the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection for use under OMB Control Number 0704–0390 through March 31, 2024. DoD proposes that OMB approve an extension of the information collection requirement, to expire three years after the approval date.

DATES: DoD will consider all comments received by January 8, 2024.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0390, using either of the following methods:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

○ *Email: osd.dfars@mail.mil.* Include OMB Control Number 0704–0390 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Jon Snyder, 571–945–5341.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 229, Taxes, and related clause at DFARS 252.229–7010; OMB Control Number 0704–0390.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Reporting Frequency: On occasion.

Number of Respondents: 10.

Responses per Respondent: 2.1, approximately.

Annual Responses: 21.

Average Burden per Response: 4 hours.

Annual Burden Hours: 84.

Needs and Uses: DoD uses this information to determine if DoD contractors in the United Kingdom have attempted to obtain relief from customs duty on vehicle fuels in accordance with contract requirements. The clause at DFARS 252.229–7010, Relief from Customs Duty on Fuel (United Kingdom), is prescribed for use in solicitations issued and contracts awarded in the United Kingdom that require the use of fuels (gasoline or diesel) and lubricants in taxis or vehicles other than passenger vehicles. The clause requires the contractor to provide the contracting officer with evidence that the contractor has initiated an attempt to obtain relief from customs duty on fuels and lubricants, as permitted by an agreement between the United States and the United Kingdom.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

[FR Doc. 2023–24691 Filed 11–7–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2023–0040; OMB Control Number 0704–0259; Req No. DARS–2024–00007–FR]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Part 216, Types of Contracts

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. DoD invites comments on: whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of DoD'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 the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection for use under Control Number 0704–0259 through March 31, 2024. DoD proposes that OMB approve an extension of the information collection requirement, to expire three years after the approval date.

DATES: DoD will consider all comments received by January 8, 2024.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0259, using either of the following methods:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

○ *Email: osd.dfars@mail.mil.* Include OMB Control Number 0704–0259 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Ziegler, 703–901–3176.

SUPPLEMENTARY INFORMATION:

Title and OMB Control Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 216, Types of Contracts, and associated clauses at Part 252.216; OMB Control Number 0704–0259.

Affected Public: Businesses or other for-profit and not-for profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Reporting Frequency: On occasion.

Number of Respondents: 111.

Responses per Respondent: Approximately 5.46.

Annual Responses: 606.

Average Burden per Response: 4 hours.

Annual Burden Hours: 2,424.

Needs and Uses: The clauses at DFARS 252.216–7000, Economic Price Adjustment—Basic Steel, Aluminum, Brass, Bronze, or Copper Mill Products; DFARS 252.216–7001, Economic Price Adjustment—Nonstandard Steel Items; and DFARS 252.216–7003, Economic Price Adjustment—Wage Rates or Material Prices Controlled by a Foreign Government, require contractors with fixed-price economic price adjustment contracts to submit information to the contracting officer regarding changes in established material prices or wage rates. The contracting officer uses this information to make appropriate adjustments to contract prices.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

[FR Doc. 2023–24689 Filed 11–7–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Req No. OS–2024–00034–FR]

Notice of Termination of the Intent To Prepare an Environmental Impact Statement for Construction and Operation of a Homeland Defense Radar in Hawaii

AGENCY: Missile Defense Agency (MDA), Department of Defense (DoD).

ACTION: Notice of termination.

SUMMARY: The DoD postponed the Homeland Defense Radar-Hawaii (HDR–H) in 2019, and no funds have been appropriated for the program since fiscal year 2022. The DoD is not moving forward with the HDR–H. As such, the MDA is terminating preparation of the Environmental Impact Statement (EIS) for the construction and operation of an HDR–H.

DATES: This termination takes effect on November 8, 2023.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Wright, MDA Public Affairs, at 571–231–8212 or by email to *mda.info@mda.mil.*

SUPPLEMENTARY INFORMATION: This notice advises the public that the MDA, as lead agency, effective immediately, no longer intends to prepare an environmental impact statement for construction and operation of an HDR–H. Therefore, the Notice of Intent announced in the **Federal Register** on June 1, 2018 (83 FR 25442–25443) is terminated.

This notice is published in accordance with sections 1503.1 and 1506.6 of the Council on Environmental Quality's Regulations (40 CFR parts 1500–1508) implementing the procedural requirements of the National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et seq.*), and the MDA's NEPA Implementing Procedures (79 FR 46410, August 8, 2014; updated on January 29, 2018).

Dated: November 2, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–24585 Filed 11–7–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the U.S. Naval Academy Board of Visitors

AGENCY: Department of the Navy, U.S. Department of Defense (DoD).

ACTION: Notice of partially closed meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the U.S. Naval Academy Board of Visitors, hereafter ''Board,'' will take place.

DATES: Open to the public, December 4, 2023, from 9 a.m. to 11 a.m. eastern time zone (ET). Closed to the public, December 4, 2023, from 11 a.m. to noon (12 p.m.) ET.

ADDRESSES: This meeting will be held at the U.S. Naval Academy, Annapolis, MD. Pending prevailing health directives, the meeting will be handicap accessible. Escort is required.

FOR FURTHER INFORMATION CONTACT: For further information, contact Major Alexandra Fitzgerald, USMC, Executive Secretary to the Board of Visitors, Office of the Superintendent, U.S. Naval Academy, Annapolis, MD 21402–5000, 410–293–1503, *afitzger@usna.edu,* or visit *https://www.usna.edu/PAO/Superintendent/bov.php.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 United States Code (U.S.C.), appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), the General Services Administration's (GSA) Federal Advisory Committee Management Final Rule (41 Code of Federal Regulations (CFR) part 102–3).

Purpose of Meeting: The U.S. Naval Academy Board of Visitors will meet to make such inquiry, as the Board deems necessary, into the state of morale and discipline, the curriculum, instruction, physical equipment, fiscal affairs, and academic methods of the Naval Academy.

Agenda

Proposed meeting agenda for December 4, 2023.

0900 Call to Order (Open to Public)
0900–1055 Opening Meeting (Open to Public)
1055–1100 Break (Open to Public)
1100–1200 Closed Meeting (Closed to Public)

Current details on the board of visitors may be found at *https://www.usna.edu/PAO/Superintendent/bov.php.*

The closed meeting from 11 a.m. to 12 p.m. on December 4, 2023, will consist of discussions of new and pending administrative or minor disciplinary infractions and non-judicial punishments involving midshipmen attending the Naval Academy to include but not limited to, individual honor or conduct violations within the Brigade, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. For this reason, a portion of this meeting will be closed to the public, as the discussion of such information cannot be adequately segregated from other topics, which precludes opening the closed meeting to the public. Accordingly, the Secretary of the Navy, in consultation with the Department of the Navy General Counsel, has determined in writing that the meeting shall be

partially closed to the public because the discussions during the closed meeting from 11 a.m. to noon (12 p.m.) will be concerned with matters protected under sections 552b(c) (5), (6), and (7) of title 5, U.S.C.

Meeting Accessibility: Pursuant to FACA and 41 CFR 102–3.140, this meeting is open to the public. Any public attendance at the meeting will be governed by prevailing health directives at the United States Naval Academy. Please contact the Executive Secretary five business days prior the meeting to coordinate access to the meeting.

Written Statements: Per section 10(a)(3) of the FACA and 41 CFR 102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration at any time, but should be received by the Designated Federal Officer at least five business days prior to the meeting date so that the comments may be made available to the Board for their consideration prior to the meeting. Written statements should be submitted via mail to 121 Blake Rd., Annapolis, MD 21402. Please note that since the Board operates under the provisions of the FACA, as amended, all submitted comments and public presentations may be treated as public documents and may be made available for public inspection, including, but not limited to, being posted on the board website.

Dated: November 2, 2023.

J.E. Koningisor,

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

[FR Doc. 2023–24638 Filed 11–7–23; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0156]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Charter Online Management and Performance System (COMPS) SE Grant Profile

AGENCY: Office of Elementary and Secondary Education (OESE), 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 December 8, 2023.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Stephanie Jones, (202) 453–7498.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Charter Online Management and Performance System (COMPS) SE Grant Profile.

OMB Control Number: 1810–NEW.

Type of Review: New ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 40.

Total Estimated Number of Annual Burden Hours: 320.

Abstract: This request is for a new OMB approval to collect the Grant Profile data from Charter School Programs (CSP) State Entity (SE) grantees. The Charter School Programs (CSP) was originally authorized under title V, part B, subpart 1, sections 5201 through 5211 of the Elementary and Secondary Education Act (ESEA) of 1965, as amended by the No Child Left Behind (NCLB) Act of 2001. For fiscal year 2017 and thereafter, ESEA has been amended by the Every Student Succeeds Act (ESSA), (20 U.S.C. 7221–7221i), which reserves funds to improve education by supporting innovation in public education and to: (2) provide financial assistance for the planning, program design, and initial implementation of charter schools; (3) increase the number of high-quality charter schools available to students across the United States; (4) evaluate the impact of charter schools on student achievement, families, and communities, and share best practices between charter schools and other public schools; (5) encourage States to provide support to charter schools for facilities financing in an amount more nearly commensurate to the amount States typically provide for traditional public schools; (6) expand opportunities for children with disabilities, English learners, and other traditionally underserved students to attend charter schools and meet the challenging State academic standards; (7) support efforts to strengthen the charter school authorizing process to improve performance management, including transparency, oversight and monitoring (including financial audits), and evaluation of such schools; and (8) support quality, accountability, and transparency in the operational performance of all authorized public chartering agencies, including State educational agencies, local educational agencies, and other authorizing entities.

The U.S. Department of Education (ED) is requesting authorization to collect data from CSP grantees within the SE program through a new online platform. In 2022, ED began development of a new data collection system, the Charter Online Management and Performance System (COMPS), designed specifically to reduce the burden of reporting for users and increase validity of the overall data. This new collection consists of questions responsive to the actions established in the program's final rule published in the **Federal Register** on July 6, 2022, as well as the SE program Notice Inviting Applications (NIA). This collection request is a consolidation of all previously established program data collection efforts and provides a more comprehensive representation of grantee performance.

Dated: November 2, 2023.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–24654 Filed 11–7–23; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10620–01–OMS]

Privacy Act of 1974; System of Records

AGENCY: Office of Inspector General, Environmental Protection Agency (EPA).

ACTION: Notice of a new system of records.

SUMMARY: The U.S. Environmental Protection Agency's (EPA) Office of Inspector General (OIG) is giving notice that it proposes to create a new a system of records pursuant to the provisions of the Privacy Act of 1974. OIG Data Analytics Enterprise is being created to store and maintain records collected by EPA OIG that are necessary in order to fulfill the responsibilities of the Inspector General Act of 1978, as amended. The EPA OIG will use this system of records to develop data models and analytical assessments that will assist with the performance of audits, evaluations, investigations, and reviews in order to identify fraud, waste, mismanagement, and abuse relating to the programs and operations of the EPA.

DATES: Persons wishing to comment on this system of records notice must do so by December 8, 2023. Routine uses for this new system of records will be effective December 8, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OMS–2023–0020, by one of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov. Follow the online instructions for submitting comments.

Email: docket_oms@epa.gov. Include the Docket ID number in the subject line of the message.

Fax: (202) 566–1752.

Mail: OMS Docket, Environmental Protection Agency, Mail Code: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery: OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OMS–2023–0020. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Controlled Unclassified Information (CUI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CUI or otherwise protected through *https://www.regulations.gov.* The *https://www.regulations.gov* website is an ''anonymous access'' system for the EPA, which means the EPA will not know your identity or contact information. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov,* 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CUI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *https://www.regulations.gov* or in hard copy at the OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. The Public Reading Room is normally 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 is (202) 566–1744, and the telephone number for the OMS Docket is (202) 566–1752. Further information about EPA Docket Center services and current operating status is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Daniel Porter, Director, Data Analytics Directorate, Office of Inspector General, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20004; phone number: 202–309–6449; email: *oig.data_analytics@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA OIG will use this system of records to develop data models and analyses in order to identify fraud, waste and abuse, and programmatic problems and deficiencies. This system of records will allow the EPA OIG to identify correlations between existing EPA data sets and other government agency data sets to identify patterns and correlations that indicate fraud and issues of program waste and abuse. EPA OIG will apply analytics and data modeling principles within this system of records to identify problems or failures in the implementation or performance of internal controls within the EPA. EPA will separately add exemptions for this system of records to the Agency's Privacy Act regulations at 40 CFR part 16.

SYSTEM NAME AND NUMBER:

OIG Data Analytics Enterprise, EPA–100.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of Inspector General, Environmental Protection Agency, 109 T.W. Alexander Drive, Durham, NC 27711.

SYSTEM MANAGER(S):

Daniel Porter, EPA Office of Inspector General (OIG), Data Analytics Directorate (DAD), Director, 1200 Pennsylvania Avenue NW, Washington, DC 20004, 202–309–6449, *porter.daniel@epa.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Inspector General Act of 1978, as amended, 5 U.S.C. 401–424 (Inspector General Act).

PURPOSE(S) OF THE SYSTEM:

Records contained in OIG Data Analytics Enterprise may be used in the course of performing audits, evaluations, and inspections; investigating individuals and entities suspected of criminal, civil, or administrative misconduct and in

supporting related judicial and administrative proceedings; or in conducting preliminary inquiries undertaken to determine whether to commence an audit, evaluation, inspection, or investigation.

CATEGORIES OF INDIVIDUALS COVERED BY SYSTEM:

The EPA OIG maintains records in OIG Data Analytics Enterprise on the following categories of individuals: current, former, and prospective EPA employees; contractors; subcontractors; recipients of Federal funds and their contractors/subcontractors and employees; grantees; sub-grantees; individuals who work on Agency grants (*e.g.,* principal investigators); lessees; licensees; persons engaged in official business with the Agency; or other persons identified by OIG or by other agencies, constituent units of the Agency, and members of the general public, in connection with the authorized functions of the OIG.

CATEGORIES OF RECORDS IN THE SYSTEM:

The OIG Data Analytics Enterprise will contain a wide variety of records to assist OIG staff in carrying out their work. Categories of records may include: information obtained from EPA business systems information, including general ledger data, bank account numbers and transactions, contracting and business ownership data, Electronic Funds Transfer Numbers, customer data, and vendor data; Agency payroll, purchase card, and travel card data; System for Award Management (*SAM.gov*) data; general case management documentation; correspondence; personally identifiable and business identifiable information, including financial, employment, time and attendance, human resources, and biometric data and Social Security Numbers; information protected by Title 13 of the U.S. Code; trade secrets data and similar proprietary data; import/export data, including Automated Export System data; law enforcement data; data containing information related to Agency grants and contracts, and other data and evidence received, collected, or generated by OIG's Data Analytics group while conducting its official duties. Social Security Numbers are maintained in the system pursuant to authority under the Inspector General Act and are collected or received and maintained in the system as necessary by OIG to carry out its statutory responsibilities under the Inspector General Act.

RECORD SOURCE CATEGORIES:

Records and information stored in this system of records are obtained from both publicly and privately available sources and various systems of records and information systems within the EPA and other Federal, State, and local agencies, Federal contractors, and non-government entities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The routine uses below are both related to and compatible with the original purpose for which the information was collected. The following general routine uses apply to this system (86 FR 62527): A, B, C, D, E, F, G, H, I, J, K, L, and M.

Additional routine uses that apply to this system are:

1. To any source, private or public, to the extent necessary to secure from such source information relevant to a legitimate EPA investigation, audit, decision, or other inquiry.

2. To a Federal, State, local, Tribal, Territorial, foreign, international, or other public authority in response to its request in connection with: the hiring, assignment, or retention of an individual; the issuance, renewal, retention, or revocation of a security clearance; the reporting of an investigation of an individual; the execution of a security or suitability investigation; the letting of a contract; or the issuance, retention, or revocation of a license, grant, award, contract, or other benefit conferred by that entity to the extent that the information is relevant and necessary to the requesting entity's decision on the matter.

3. To the Department of Justice (DOJ) or any other Federal agency to the extent necessary to obtain their advice relevant to an OIG matter, or that has an interest in the record in connection with determining whether disclosure thereof is required by the Freedom of Information Act (FOIA) (5 U.S.C. 552).

5. To the Department of the Treasury and the Department of Justice when EPA is seeking an ex parte court order to obtain taxpayer information from the Internal Revenue Service.

6. To the news media and public when a public interest justifies the disclosure of information on public events such as indictments or similar activities and such disclosure would not cause an unwarranted invasion of personal privacy.

7. To the public when the matter under audit or investigation has become public knowledge, or when the Inspector General determines that such disclosure is necessary to preserve confidence in the integrity of the OIG audit or investigative process or is necessary to demonstrate the accountability of EPA officers, employees, or individuals covered by this system, unless it is determined that disclosure of the specific information in the context of a particular case could reasonably be expected to constitute an unwarranted invasion of personal privacy.

8. To Members of Congress and the public in the OIG's Semiannual Report to Congress when the Inspector General determines that the matter reported is significant.

9. To a Federal agency responsible for considering suspension or debarment action where such record would be relevant to such action.

10. In response to a lawful subpoena issued by a Federal agency.

11. To a public or professional licensing organization if the record indicates, either by itself or in combination with other information, a violation or potential violation of professional standards, or reflects on the moral, educational, or professional qualifications of an individual who is licensed or who is seeking to become licensed.

12. To any person when disclosure of the record is needed to enable the recipient of the record to take action to recover money or property of the EPA, when such recovery will accrue to the benefit of the United States, or when disclosure of the record is needed to enable the recipient of the record to take appropriate disciplinary action to maintain the integrity of EPA programs or operations.

13. To the Office of Government Ethics to comply with agency reporting requirements in 5 CFR 2638.206.

14. To a foreign government or international organization pursuant to an international treaty, convention, implementing legislation, or executive agreement entered into by the United States.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

These records are maintained electronically on computer storage devices managed by the Office of Inspector General, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460. Electronically stored information is hosted at the EPA National Computer Center (NCC), 109 TW Alexander Drive, Research Triangle Park, Durham, NC 27711, in agency-owned cloud and on-premise environments. Paper records are maintained at the Office of the

Inspector General at 1200 Pennsylvania Avenue NW, Washington, DC 20460.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by search criteria that include names of individuals, names of businesses, identifying particulars, organizations, Social Security Number, EPA ID number, or driver's license number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained and disposed of in accordance with EPA Records Retention Schedules approved by the National Archives and Records Administration (NARA).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Security controls used to protect personal sensitive data in OIG Data Analytics Enterprise are commensurate with those required for an information system rated MODERATE for confidentiality, integrity, and availability, as prescribed in National Institute of Standards and Technology (NIST) Special Publication, 800–53, ''Security and Privacy Controls for Information Systems and Organizations,'' Revision 5.

1. Administrative Safeguards: All users must take annual mandatory Security Awareness and Privacy training as provided by the Agency. Additionally, staff determined to have significant security responsibilities are also required to complete role-based training (RBT).

2. Technical Safeguards: Access to electronic records is restricted to the OIG staff and contractors individually authorized to access the electronic system. Access is restricted based on assigned roles and responsibilities. Authentication to the system occurs through the Agency's Active Directory Domain Controller. Passwords must meet complexity requirements and are changed periodically, in accordance with OIG policies. Also, all devices that connect to the system use a screen lock; both (screen lock and password) are enforced by Agency policy.

3. Physical Safeguards: Electronic records are stored on servers maintained in a locked facility that is secured at all times. All electronic media are kept in limited-access areas during duty hours and in locked offices during nonduty hours and are used only by authorized screened personnel.

RECORD ACCESS PROCEDURES:

Pursuant to 5 U.S.C. 552a(j)(2), (k)(2), and (k)(5), certain records maintained in the OIG Data Analytics Enterprise are exempt from specific access and accounting provisions of the Privacy Act. See 40 CFR 16.11 and 16.12, However, EPA may, in its discretion, grant individual requests for access if it determines that the exercise of these rights will not interfere with an interest that the exemption is intended to protect. Requests for access must be made in accordance with the procedures described in EPA's Privacy Act regulations at 40 CFR part 16.

CONTESTING RECORD PROCEDURES:

Pursuant to 5 U.S.C. 552a(j)(2), (k)(2), and (k)(5), certain records maintained in the OIG Data Analytics Enterprise are exempt from specific access and accounting provisions of the Privacy Act. See 40 CFR 16.11 and 16.12. However, EPA may, in its discretion, grant individual requests for correction and amendment if it determines that the exercise of these rights will not interfere with an interest that the exemption is intended to protect. Requests for correction and amendment must identify the record to be changed and the correction sought, and must be made in accordance with the procedures described in EPA's Privacy Act regulations at 40 CFR part 16.

NOTIFICATION PROCEDURES:

Individuals who wish to be informed whether a Privacy Act system of records maintained by EPA contains any record pertaining to them, should make a written request to the EPA, Attn: Agency Privacy Officer, MC 2831T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, or by email at: *privacy@epa.gov.* A full description of EPA's Privacy Act procedures is included in EPA's Privacy Act regulations at 40 CFR part 16.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

EPA has exempted records maintained in this system from 5 U.S.C. 552a(c)(3) and (4); 5 U.S.C. 552a(d); 5 U.S.C. 552a(e)(1), (2) and (3); 5 U.S.C. 552a(e)(4)(G) and (H); 5 U.S.C. 552a(e)(5) and (8); 5 U.S.C. 552a(f)(2) through (5); and 5 U.S.C. 552a(g) of the Privacy Act pursuant to 5 U.S.C. 552a(j)(2). EPA has also exempted records maintained in this system from 5 U.S.C. 552a(c)(3), 5 U.S.C. 552a(d), 5 U.S.C. 552a(e)(1), 5 U.S.C. 552a(e)(4)(G) and (H) and 5 U.S.C. 552a(f)(2) through (5) of the Privacy Act under 5 U.S.C. 552a(k)(2). EPA has also exempted records maintained in this system from 5 U.S.C. 552a(c)(3) and 5 U.S.C. 552a(d) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(5). An exemption rule for this record system has been promulgated in accordance with the requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c) and (e) and published in 40 CFR part 16. In addition, when exempt records received from other systems of records become part of this system, EPA also claims the same exemptions for those records that are claimed for the prior system(s) of records from which they were a part and claims any additional exemptions set forth here.

HISTORY:

None.

Vaughn Noga,

Senior Agency Official for Privacy.

[FR Doc. 2023–24231 Filed 11–7–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2023–0014; FRL–10969–02–OAR]

Clean Air Act Advisory Committee (CAAAC): Notice of Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the Environmental Protection Agency (EPA) is announcing a public meeting of the Clean Air Act Advisory Committee (CAAAC). The EPA renewed the CAAAC charter on October 31, 2022, to provide independent advice and counsel to EPA on economic, environmental, technical, scientific and enforcement policy issues associated with implementation of the Clean Air Act of 1990.

DATES: The CAAAC will hold its next hybrid public meeting; in-person at EPA Headquarters, Washington, DC and virtual on Thursday, December 7, 2023, from 9 a.m. to 4 p.m. (EST). Members of the public may register to attend or listen to the meeting or provide comments, by emailing *caaac@epa.gov* by 5:00 (EST) December 5, 2023.

FOR FURTHER INFORMATION CONTACT: Lorraine Reddick, Designated Federal Official, Clean Air Act Advisory Committee (6103A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–564–1293; email address: *reddick.lorraine@epa.gov.* Additional information about this meeting, the CAAAC, and its subcommittees and workgroups can be found on the CAAAC website: *http://www.epa.gov/caaac/.*

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. app. 2 section 10(a)(2),

notice is hereby given that the Clean Air Act Advisory Committee will hold its next hybrid public meeting on Thursday, December 7, 2023, from 9 a.m. to 4 p.m. (EST).

The committee agenda and any documents prepared for the meeting will be publicly available on the CAAAC website at *http://www.epa.gov/caaac/* prior to the meeting. Thereafter, these documents, together with CAAAC meeting minutes, will be available on the CAAAC website or by contacting the Office of Air and Radiation Docket and requesting information under docket EPA–HQ–OAR–2023–0014. The docket office can be reached by email at: *a-and-r-Docket@epa.gov* or FAX: 202–566–9744.

For information on access or services for individuals with disabilities, please contact Lorraine Reddick at *reddick.lorraine@epa.gov,* preferably at least 7 days prior to the meeting to give EPA as much time as possible to process your request.

Lorraine Reddick,

Designated Federal Officer, Office of Air Policy and Program Support.

[FR Doc. 2023–24698 Filed 11–7–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1166; FR ID 183018]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before January 8, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

OMB Control Number: 3060–1166.

Title: Section 1.21001, Participation in Competitive Bidding for Support; Section 1.21002, Prohibition of Certain Communications During the Competitive Bidding Process.

Form Number: N/A

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and State, local or Tribal governments.

Number of Respondents and Responses: 750 respondents and 750 responses.

Estimated Time per Response: 1.5 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection 47 U.S.C. 154, 254 and 303(r).

Total Annual Burden: 1,125 hours.

Total Annual Cost: No cost.

Needs and Uses: The information required by section 1.21001 of the Commission's rules that is collected under this information collection is used by the Commission to determine whether applicants are eligible to participate in auctions for Universal Service Fund support. The reports of prohibited communications made or received by an auction applicant required by section 1.21002 of the Commission's rules that are collected under this information collection enable the Commission to ensure that no bidder gains an unfair advantage over other bidders in its auctions for universal service support and thus enhance the competitiveness and fairness of Commission's auctions for universal service support.

On November 18, 2011, the Commission released an order in which it comprehensively reformed and modernized the universal service and intercarrier compensation systems to ensure that robust, affordable voice and broadband service, both fixed and mobile, are available to Americans throughout the nation. *Connect America Fund et al.,* Order and Further Notice of Proposed Rulemaking, FCC 11–161 (*USF/ICC Transformation Order*). In the *USF/ICC Transformation Order,* the Commission, among other things, adopted rules to implement these reforms, including rules in part 1, subpart AA of the Commission's rules governing competitive bidding for universal service support generally. *See* 47 CFR 1.21001–1.21004.

On October 27, 2020, the Commission adopted a Report and Order in which it, among other things, amended sections 1.21001 and 1.21002 of its existing part 1, subpart AA general universal service competitive bidding rules to codify policies and procedures applicable to the universal service auction application process that have been adopted in its recent universal service auctions, better align provisions in the universal service competitive bidding rules with like provisions in the Commission's spectrum auction rules, and make other updates for consistency, clarification, and other purposes that would apply in all universal service auctions. *Establishing a 5G Fund for Rural America,* Report and Order, FCC 20–150 (*5G Fund Report and Order*). Sections 1.21001 and 1.21002 in the Commission's Part 1, Subpart AA rules, as amended in the *5G Fund Report and Order,* apply to applicants seeking to participate in Commission auctions for universal service support.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–24645 Filed 11–7–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1281; FR ID 183731]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 8, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–1281.

Title: 3.7 GHz Service Licensee and Earth Station Operator Agreements; 3.7 GHz Service Licensee Engineering Analysis.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 30 respondents and 30 responses.

Estimated Time per Response: 2 hours–5 hours.

Frequency of Response: Recordkeeping requirement; on occasion reporting requirement; third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in sections 1, 2, 4(i), 4(j), 5(c), 201, 302, 303, 304, 307(e), 309, and 316 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(j), 155(c), 201, 302, 303, 304, 307(e), 309, and 316.

Total Annual Burden: 120 hours.

Annual Cost Burden: No cost.

Needs and Uses: Under this new information collection, the Commission will collect information that will be used to ensure that 3.7–4.2 GHz band stakeholders adopt practices to ensure the effective and efficient use of the band in a manner that protects incumbent C-band operations. This collection will support the efficient and expeditious clearing of the lower portion of the band while minimizing the risk of harmful interference to incumbent operations. This information collection must be renewed as the C-band transition relocation process is still underway.

The transition relocation process began in 2020. Initial Transition Plans were filed on June 19, 2020 with final Transition Plans due August 14, 2020. Throughout this process, the Wireless Telecommunications Bureau (Bureau) opened limited windows to amend their Transition Plans on several occasions. In addition to submitting and modifying Transition Plans during these periods, eligible space station operators were required to file quarterly status reports with the Commission beginning on December 31, 2020 to demonstrate their efforts to ensure a timely transition.

On May 15, 2023, the Bureau announced procedures for filing C-band Phase II Certifications of Accelerated Relocation and implementation of the Commission's incremental reduction plan for Phase II Accelerated Relocation Payments as part of the ongoing transition. The C-Band Relocation Payment Clearinghouse (RPC) is responsible for disbursing the Accelerated Relocation Payments within a certain time period. On June 1, 2023, space station operators began submitting their Phase II certifications. Also on June 1, 2023, the Bureau opened a limited, final window for eligible space station operators to file modified Transition Plans to accurately account for any updates since the last filing window in 2021.

Phase II's deadline to complete the transition of space station operations to the upper 200 megahertz of the band was originally set for December 5, 2023. Instead, on August 10, 2023, the last of the Phase II Certifications was deemed granted. Even though Phases I and II of the satellite transition are complete, the Commission continues to work through the C-band relocation process. Most recently, on October 13, 2023, the Bureau released a Public Notice seeking comment on proposed deadlines for claimants to submit reimbursement claims. The Public Notice stated that the RPC's operations are currently scheduled to conclude on June 30, 2025, which is still more than a year and a half away. The relocation of the fixed service licensees is also ongoing.

As mentioned in the initial request for this information collection, it is important to continue to collect information to promote safety of operations in the band and guarantee access to important coordination and technical aspects of the transition. Because this process remains ongoing, this information collection should be renewed to ensure that a complete set of information is maintained for stakeholders to understand coordination measures necessary to protect band operations. If this collection were to expire now, stakeholders would be missing ongoing information about the transition process. Renewing this collection will provide stakeholders with complete information instead of an information collection that ends before the entire transition process is officially accomplished in 2025.

The Commission now seeks approval for renewal of its currently approved collection of information under OMB Control Number 3060–1281. While the majority of the collection required one-time filings that are already complete, there is an ongoing requirement that 3.7 GHz Service Licensees maintain a copy of private agreements to modify any earth station operations in the 4000–4200 MHz in their station files.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–24646 Filed 11–7–23; 8:45 am]

BILLING CODE P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0484; FR ID 183694]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before January 8, 2024. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

OMB Control Number: 3060–0484.

Title: Part 4 of the Commission's Rules Concerning Disruptions to Communications.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; not-for-profit institutions; State, local or Tribal government.

Number of Respondents and Responses: 3,224 respondents; 201,848 responses.

Estimated Time per Response: 1 hour–2 hours (average per response).

Frequency of Response: On occasion and annual reporting requirements and recordkeeping requirement.

Obligation to Respond: Mandatory and Voluntary. Statutory authority for this collection is contained in sections 1, 4(i), 4(j), 4(n), 4(o), 201(b), 214, 218, 251(e)(3), 251(e)(4), 254, 301, 303(b), 303(g), 303(r), 307, 309(a), 309(j), 316, 332, and 403 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 154(i)–(j), (n), & (o), 201(b), 214, 218, 251(e)(3), 251(e)(4), 254, 301, 303(b), 303(g), 303(r), 307, 309(a), 332, 403, 615, 615a–1, and 1302.

Total Annual Burden: 170,802 hours.

Total Annual Cost: No cost.

Needs and Uses: The general purpose of the Commission's Part 4 rules is to gather sufficient information regarding disruptions to telecommunications to facilitate FCC monitoring, analysis, and investigation of the reliability and security of voice, paging, and interconnected Voice over Internet Protocol (interconnected VoIP) communications services, and to identify and act on potential threats to our Nation's telecommunications infrastructure. The Commission uses this information collection to identify the duration, magnitude, root causes, and contributing factors with respect to significant outages, and to identify outage trends; support service restoration efforts; and help coordinate with public safety officials during times of crisis. The Commission also maintains an ongoing dialogue with reporting entities, as well as with the communications industry at large, generally regarding lessons learned from the information collection in order to foster a better understanding of the root causes of significant outages and to explore preventive measures in the future so as to mitigate the potential scale and impact of such outages.

In a Second Report and Order adopted on November 18, 2022, as FCC 22–88, the Commission adopted rules harmonizing its 911 special facility notifications rules such that outage notifications from covered 911 service providers and originating service providers (OSPs) will include the same notification content, be transmitted by the same means, and with the same timing and frequency. In addition, in a Report and Order adopted on July 20, 2023, as FCC 23–57. the Commission extended outage reporting and notification requirements to outages affecting 988 special facilities in order to ensure that officials responsible for overseeing the 988 Suicide & Crisis Lifeline (988 Lifeline), which is a 24/7 hotline available to people in suicidal crisis and mental health distress, receive timely and actionable information about 988 service outages. The Commission's existing Part 4 rules allow certain federal, state, and Tribal Nation agencies (Participating Agencies) to access to certain geographically relevant outage reports filed in the Commission's Network Outage Reporting System (NORS).

The information collections and record keeping provisions adopted in the 2022 Second Report and Order will harmonize and standardize 911 outage reporting, which assists 911 special facilities in receiving and responding to service outage notification, and the information we are requiring to be contained in the reports will improve the speed and accuracy of responses to service outages by 911 service providers, which promotes public safety.

The information collections adopted in the 2023 988 Report and Order will allow the Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Veterans Affairs (VA), and the 988 Lifeline administrator, which are the entities responsible for overseeing the 988 Lifeline, to provide the public with notice of outages impacting 988 services, and information how they can access the 988 Lifeline despite the outage. SAMHSA, the VA, and the 988 Lifeline administrator can also take steps to reroute 988 calls to available crisis centers and take other steps to reduce the amount of time that individuals would need to wait before they receive assistance. Notice about outages will allow SAMHSA, the VA, and the Lifeline administrator to continue meeting the immediate health needs of people in suicidal crisis and mental health distress. The Commission will also be able to improve 988

reliability by using this information to analyze outage trends and identify best practices to prevent and mitigate outages.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–24647 Filed 11–7–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1085, OMB 3060–1280; FR ID 183722]

Information Collections Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before December 8, 2023.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–1085.

Title: Section 9.11, Interconnected Voice Over internet Protocol (VoIP) E911 Compliance; Section 9.12, Implementation of the NET 911 Improvement Act of 2008: Location Information From Owners and Controllers of 911 and E911 Capabilities.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households; business or other for-profit entities; not-for-profit institutions; State, local or Tribal government.

Number of Respondents: 29 respondents; 13,783,364 responses.

Estimated Time per Response: 0.09 hours (five minutes).

Frequency of Response: One-time, on occasion, third party disclosure requirement, and recordkeeping requirement.

Obligation to Respond: Statutory authority for this information collection is contained in 47 U.S.C. 151, 151–154, 152(a), 155(c), 157, 160, 201, 202, 208, 210, 214, 218, 219, 222, 225, 251(e), 255, 301, 302, 303, 307, 308, 309, 310, 316, 319, 332, 403, 405, 605, 610, 615, 615 note, 615a, 615b, 615c, 615a-1, 616, 620, 621, 623, 623 note, 721, and 1471.

Total Annual Burden: 1,262,271 hours.

Total Annual Cost: $202,992,000.

Needs and Uses: The Commission is obligated by statute to promote ''safety of life and property'' and to ''encourage and facilitate the prompt deployment throughout the United States of a seamless, ubiquitous, and reliable end-to-end infrastructure'' for public safety. Congress has established 911 as the national emergency number to enable all citizens to reach emergency services directly and efficiently, irrespective of whether a citizen uses wireline or wireless technology when calling for help by dialing 911. Efforts by Federal, State and local government, along with the significant efforts of wireline and wireless service providers, have resulted in the nearly ubiquitous deployment of this life-saving service.

The Order the Commission adopted on May 19, 2005, sets forth rules requiring providers of VoIP services that interconnect with the nation's existing public switched telephone network (interconnected VoIP services) to supply E911 capabilities to their customers.

To ensure E911 functionality for customers of VoIP service providers the Commission requires the following information collections:

A. *Location Registration.* Requires providers to interconnected VoIP services to obtain location information from their customers for use in the routing of 911 calls and the provision of location information to emergency answering points.

B. *Provision of Automatic Location Information (ALI).* Interconnected VoIP service providers will place the location information for their customers into, or make that information available

through, specialized databases maintained by local exchange carriers (and, in at least one case, a state government) across the country.

C. *Customer Notification.* Requires that all providers of interconnected VoIP are aware of their interconnected VoIP service's actual E911 capabilities. That all providers of interconnected VoIP service specifically advise every subscriber, both new and existing, prominently and in plain language, the circumstances under which E911 service may not be available through the interconnected VoIP service or may be in some way limited by comparison to traditional E911 service.

D. *Record of Customer Notification.* Requires VoIP providers to obtain and keep a record of affirmative acknowledgement by every subscriber, both new and existing, of having received and understood this advisory.

E. *User Notification.* In addition, in order to ensure to the extent possible that the advisory is available to all potential users of an interconnected VoIP service, interconnected VoIP service providers must distribute to all subscribers, both new and existing, warning stickers or other appropriate labels warning subscribers if E911 service may be limited or not available and instructing the subscriber to place them on or near the customer premises equipment used in conjunction with the interconnected VoIP service.

Section 506 of RAY BAUM'S Act

Section 506 of RAY BAUM'S Act, which requires the Commission to ''consider adopting rules to ensure that the dispatchable location is conveyed with a 9–1–1 call, regardless of the technological platform used and including with calls from multi-line telephone system.'' RAY BAUM'S Act also states that, ''[i]n conducting the proceeding . . . the Commission may consider information and conclusions from other Commission proceedings regarding the accuracy of the dispatchable location for a 9–1–1 call . . . .'' RAY BAUM'S Act defines a ''9–1–1 call'' as a voice call that is placed, or a message that is sent by other means of communication, to a PSAP for the purpose of requesting emergency services.

As part of implementing section 506 of RAY BAUM'S Act, on August 1, 2019, the Commission adopted a *Report and Order* (*2019 Order*) amending, among other things, its 911 Registered Location and customer notification requirements applicable to VoIP service providers.

The Commission's *2019 Order* changed the wording of section 9.11's Registered Location requirements to facilitate the provision of automated dispatchable location in fixed and non-fixed environments. For non-fixed environments, the rule requires automated dispatchable location, if technically feasible. If not technically feasible, VoIP service providers may fall back to registered location, alternative location information for 911 calls, or a national emergency call center. Regarding customer notification requirements, the Commission afforded service providers flexibility to use any conspicuous means to notify end users of limitations in 911 service. In sum, the requirements adopted in the *2019 Order* leverage technology advancements since the 2005 *Order,* build upon the existing Registered Location requirement, expand options for collecting and supplying end-user location information with 911 calls, are flexible and technologically neutral from a compliance standpoint and serve a vital public safety interest.

NET 911 Act

The NET 911 Act explicitly imposes on each interconnected Voice over Internet Protocol (VoIP) provider the obligation to provide 911 and E911 service in accordance with the Commission's existing requirements. In addition, the NET 911 Act directs the Commission to issue regulations by no later than October 21, 2008 that ensure that interconnected VoIP providers have access to any and all capabilities they need to satisfy that requirement.

On October 21, 2008, the Commission released a *Report and Order* (*2008 Order*), FCC 08–249, WC Docket No. 08–171, that implements certain key provisions of the NET 911 Act. As relevant here under the Paperwork Reduction Act (PRA), the Commission requires an owner or controller of a capability that can be used for 911 or E911 service to make that capability available to a requesting interconnected VoIP provider under certain circumstances. In particular, an owner or controller of such capability must make it available to a requesting interconnected VoIP provider if that owner or controller either offers that capability to any commercial mobile radio service (CMRS) provider or if that capability is necessary to enable the interconnected VoIP provider to provide 911 or E911 service in compliance with the Commission's rules. The information collection requirements contained in this collection guarantee continued cooperation between interconnected VoIP service providers and Public Safety Answering Points (PSAPs) in complying with the Commission's E911 requirements.

OMB Control Number: 3060–1280.

Title: E911 Compliance for Fixed Telephony and Multi-line Telephone Systems.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions and State, local, and Tribal government.

Number of Respondents and Responses: 1,397,677 respondents; 46,728,330 responses.

Estimated Time per Response: 0.016 hours (one minute).

Frequency of Response: One-time, on occasion, third party disclosure requirement, and recordkeeping requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 152(a), 155(c), 157, 160, 201, 202, 208, 210, 214, 218, 219, 222, 225, 251(e), 255, 301, 302, 303, 307, 308, 309, 310, 316, 319, 332, 403, 405, 605, 610, 615, 615 note, 615a, 615b, 615c, 615a–1, 616, 620, 621, 623, 623 note, 721, and 1471.

Total Annual Burden: 779,266 hours.

Total Annual Cost: $1,834,020.

Needs and Uses: The Commission is obligated by statute to promote ''safety of life and property'' and to ''encourage and facilitate the prompt deployment throughout the United States of a seamless, ubiquitous, and reliable end-to-end infrastructure'' for public safety. Congress has established 911 as the national emergency number to enable all citizens to reach emergency services directly and efficiently, irrespective of whether a citizen uses wireline or wireless technology when calling for help by dialing 911. Efforts by Federal, State and local government, along with the significant efforts of wireline and wireless service providers, have resulted in the nearly ubiquitous deployment of this life-saving service.

Section 506 of RAY BAUM'S Act requires the Commission to ''consider adopting rules to ensure that the dispatchable location is conveyed with a 9–1–1 call, regardless of the technological platform used and including with calls from multi-line telephone system.'' RAY BAUM'S Act also states that, ''[i]n conducting the proceeding . . . the Commission may consider information and conclusions from other Commission proceedings regarding the accuracy of the dispatchable location for a 9–1–1 call . . . .'' RAY BAUM'S Act defines a ''9–1–1 call'' as a voice call that is placed, or a message that is sent by other means

of communication, to a Public Safety Answering Point (PSAP) for the purpose of requesting emergency services.

As part of implementing section 506 of RAY BAUM'S Act, on August 1, 2019, the Commission adopted a *Report and Order* (*2019 Order*), set forth rules requiring Fixed Telephony providers and MLTS providers to ensure that dispatchable location is conveyed with 911 calls.

The Commission's *2019 Order* adopted §§ 9.8(a) and 9.16(b)(3)(i), (ii), and (iii) to facilitate the provision of automated dispatchable location. For Fixed Telephony and in fixed Multi-line Telephone Systems (MLTS) environments, respective providers must provide automated dispatchable location with 911 calls. For on-premises, non-fixed devices associated with an MLTS, the MLTS operator or manager must provide automated dispatchable location to the appropriate PSAP when technically feasible; otherwise they must provide either dispatchable location based on end-user manual update, or alternative location information. For off-premises MLTS calls to 911, the MLTS operator or manager must provide (1) dispatchable location, if technically feasible, or, otherwise, either (2) manually-updated dispatchable location, or (3) enhanced location information, which may be coordinate-based, consisting of the best available location that can be obtained from any available technology or combination of technologies at reasonable cost. The requirements adopted in the *2019 Order* account for variance in the feasibility of providing dispatchable location for non-fixed MLTS 911 calls, and the means available to provide it. The information collection requirements associated with these rules will ensure that Fixed Telephony and MLTS providers have the means to provide 911 callers' locations to PSAPs, thus reducing response times for emergency services.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–24648 Filed 11–7–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201175–007.

Agreement Name: Port of NY/NJ Sustainable Services Agreement.

Parties: APM Terminals Elizabeth, LLC; Port Liberty Bayonne LLC; Maher Terminals LLC; Port Liberty New York LLC; Port Newark Container Terminal LLC; Red Hook Container Terminal, LLC.

Filing Party: Carol Lambos; The Lambos Firm LLP.

Synopsis: The Amendment reflects the name changes of member companies GCT Bayonne LP and GCT New York LP to Port Liberty Bayonne LLC and Port Liberty LLC respectively.

Proposed Effective Date: 10/27/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/8136.

Dated: November 3, 2023.

Carl Savoy,

Federal Register Alternate Liaison Officer.

[FR Doc. 2023–24677 Filed 11–7–23; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Notice of Board Meeting

DATES: November 14, 2023 at 10 a.m. EST

ADDRESSES: Telephonic. Dial-in (listen only) information: Number: 1–202–599–1426, Code: 675 746 624#; or via web: *https://teams.microsoft.com/l/meetup-join/19%3ameeting_OTIxOTM4MzAtYTUyOC00NzNkLWFkMTUtZGQ3ODVhZTY0OGQx%40thread.v2/0?context=%7b%22Tid%22%3a%223f6323b7-e3fd-4f35-b43d-1a7afae5910d%22%2c%22Oid%22%3a%2241d6f4d1-9772-4b51-a10d-cf72f842224a%22%7d.*

FOR FURTHER INFORMATION CONTACT: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

SUPPLEMENTARY INFORMATION:

Board Meeting Agenda

Open Session

1. Approval of the October 24, 2023, Board Meeting Minutes
2. Monthly Reports
   (a) Participant Report
   (b) Investment Report
   (c) Legislative Report
3. Quarterly Reports
   (d) Metrics
4. Internal Audit Update
5. Participant Survey Report
6. OPR Annual Report
7. TSP Investment Option Benchmark Study

Closed Session

8. Information covered under 5 U.S.C. 552b (c)(6) and (c)(10).

Authority: 5 U.S.C. 552b (e)(1).

Dated: November 2, 2023.

Dharmesh Vashee,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2023–24642 Filed 11–7–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0823]

Real-Time Oncology Review; 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 ''Real-Time Oncology Review (RTOR).'' The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected new drug applications (NDAs) and biologics license applications (BLAs) with oncology indications for review under RTOR. This guidance finalizes the draft guidance of the same title issued on July 22, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on November 8, 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–2022–D–0823 for ''Real-Time Oncology Review (RTOR).'' 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: R. Angelo De Claro, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2173, Silver Spring, MD 20993, 301–796–4415; 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Real-Time Oncology Review (RTOR).'' The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected NDAs and BLAs with oncology indications for review under RTOR.

The FDA Oncology Center of Excellence, in collaboration with the Office of Oncologic Diseases, commenced RTOR in February 2018 to facilitate earlier submission of topline results (*i.e.,* efficacy and safety results from clinical studies before the study report is completed) and datasets, after database lock, to support an earlier start to the FDA application review. The intent of RTOR is to provide FDA reviewers earlier access to data, to identify data quality and potential review issues, and to potentially enable early feedback to the applicant, which can allow for a more streamlined and efficient review process. RTOR also involves early engagement with the applicant to discuss the submission timelines for RTOR components and the full application submission. RTOR does not alter the review performance goals and timelines associated with the applications, including as described in the Prescription Drug User Fee Amendments. Participation by the applicant is voluntary and acceptance into RTOR does not guarantee or influence approval of the application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR.

This guidance finalizes the draft guidance entitled ''Real-Time Oncology Review (RTOR)'' issued on July 22, 2022 (87 FR 43870). FDA considered comments received on the draft guidance as the guidance was finalized. The final guidance includes (1) clarification of terminologies used in the guidance, (2) clarification on the submission process, and (3) additional changes to align the guidance with the RTOR website.

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 ''Real-Time Oncology Review (RTOR).'' 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 the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 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; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

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: November 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–24712 Filed 11–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of 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 Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

Date: December 5–7, 2023.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Lee G. Klinkenberg, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20852, 301–761–7749, *lee.klinkenberg@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24634 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session can be accessed from the Fogarty International Center website (*https://www.fic.nih.gov/About/Advisory/Pages/default.aspx*).

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: Fogarty International Center Advisory Board.

Date: February 5–6, 2024.

Closed: February 5, 2024, 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate the second level of grant applications.

Place: Fogarty International Center, National Institutes of Health, Lawton Chiles International House (Stone House), 16 Center Drive, Conference Room Bethesda, MD 20892.

Open: February 6, 2024, 9:00 a.m. to 3:00 p.m.

Agenda: Update and discussion of current and planned Fogarty International Center activities.

Place: Fogarty International Center, National Institutes of Health, Lawton Chiles International House (Stone House), 16 Center Drive, Conference Room Bethesda, MD 20892 (Virtual Meeting).

Meeting Access: https://www.fic.nih.gov/About/Advisory/Pages/default.aspx.

Contact Person: Kristen Weymouth, Executive Secretary, Fogarty International Center, 31 Center Drive, Room B2C02, Bethesda, MD 20892, 301–495–1415, *kristen.weymouth@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Persons listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campusaccess-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.fic.nih.gov/About/Advisory/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24627 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance to view the meeting, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: January 24, 2024.

Open: 10:00 a.m. to 3:00 p.m.

Agenda: Report of the Director, NIDCR and concept clearances.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lynn M. King, Ph.D., Executive Secretary, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892–4878, (301) 594–5006, *Lynn.King@nih.gov.*

Information is also available on the Institute's/Center's home page: *https://www.nidcr.nih.gov/about-us/advisory-committees/advisory-council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: November 3, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24706 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Phase 2 Clinical Trials in Neurology.

Date: December 7, 2023.

Time: 3:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Iqbal Sayeed, Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/DHHS NSC, 6001 Executive Boulevard, Rockville, MD 20852, 301–496–9223, *iqbal.sayeed@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Clinical Trial Readiness for Rare Neurological and Neuromuscular Diseases/Functional Neurological Disorders.

Date: December 15, 2023.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Ana Olariu, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/DHHS NSC, 6001 Executive Boulevard, Rockville, MD 20852, 301–496–9223, *Ana.Olariu@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: November 3, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24702 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Special Emphasis Panel; Assessment of TBI-Related ADRD Pathology Review (U01).

Date: December 1, 2023.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Mir Ahamed Hossain, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/DHHS NSC, 6001 Executive Blvd., Rockville, MD 20852, 301–496–9223, *mirahamed.hossain@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24631 Filed 11–7–23; 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 Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurological and Neuropsychological Injuries and Disorders.

Date: November 30, 2023.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Todd Everett White, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3962, *todd.white@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: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24632 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; National Addiction and HIV Data Archive Program.

Date: December 1, 2023.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Brian Stefan Wolff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 480–1448, *brian.wolff@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24628 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Developmental Centers for AIDS Research (P30 Clinical Trial Not Allowed).

Date: December 11–12, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kristina S. Wickham, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22B, Rockville, MD 20852, 301–761–5390, *kristina.wickham@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Centers for AIDS Research (P30 Clinical Trial Not Allowed).

Date: December 11–12, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kristina S. Wickham, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22B, Rockville, MD 20852, 301–761–5390, *kristina.wickham@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24635 Filed 11–7–23; 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: Center for Scientific Review Special Emphasis Panel; PAR Panel: International Bioethics Research Education, Curriculum Development and Training.

Date: December 4, 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: Annie Laurie McRee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 100, Bethesda, MD 20892, (301) 827–7396, *mcreeal@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Social and Community Influences Across the Lifecourse.

Date: December 5, 2023.

Time: 10:00 a.m. to 5:00 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: Kate Fothergill, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3142, Bethesda, MD 20892, 301–435–1782, *fothergillke@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Immune-Mediated Diseases and Bacterial Host Interactions.

Date: December 5, 2023.

Time: 11:00 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: Carmen Angeles Ufret-Vincenty, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–0912, *carmen.ufret-vincenty@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: November 3, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24704 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Research Education Program (R25 Clinical Trial Not Allowed).

Date: December 1, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G33, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Poonam Pegu, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G33, Rockville, MD 20852, 240–292–0719, *poonam.pegu@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 3, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24708 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Spore (P50) Review SEP–V.

Date: February 6–7, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Michael E. Lindquist, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850, *mike.lindquist@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) Review SEP–D.

Date: February 14–15, 2024.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Shree Ram Singh, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850, 240–672–6175, *singhshr@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 3, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24707 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Special Emphasis Panel; Development and Validation of Models for ADRD.

Date: November 17, 2023.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Mirela Milescu, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/DHHS NSC, 6001 Executive Boulevard, Rockville, MD 20852, 301–496–5720, *mirela.milescu@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: November 3, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24701 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below at least (7) business days prior to the meeting. The meeting can be accessed from the NIH Videocasting at the following link: *https://videocast.nih.gov/.*

Name of Committee: Interagency Autism Coordinating Committee.

Date: January 24, 2024.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To discuss committee business, updates, and issues related to autism research and services activities.

Place: National Institute of Mental Health (NIMH), Neuroscience Center (NSC), 6001 Executive Boulevard, First Floor Conference Room, Rockville, MD 20852.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (*www.iacc.hhs.gov*) prior to the meeting. Pre-registration is recommended.

Deadlines: Public Comment Due Date: Tuesday, January 9, by 5:00 p.m. ET.

Public Comment Guidelines: For public comment instructions, see below.

Contact Person: Ms. Rebecca Martin, Office of National Autism Coordination, National Institute of Mental Health, NIH, Phone: 301–435–0886, Email: *IACCPublicInquiries@mail.nih.gov*.

Public Comments:

The IACC welcomes written and oral public comments from members of the autism community and asks the community to review and adhere to its Public Comment Guidelines. In the *2021–2023 IACC Strategic Plan,* the IACC lists the ''Spirit of Collaboration'' as one of its core values, stating that, ''We will treat others with respect, listen with open minds to the diverse lived experiences of people on the autism spectrum and their families, consider multiple solutions, and foster discussions where participants can comfortably share different opinions.'' In keeping with this core value, the IACC and the NIMH Office of National Autism Coordination (ONAC) ask that members of the public who provide public comments or participate in meetings of the IACC also adhere to this core value.

A limited number of slots are available for individuals to provide a 3-minute summary or excerpt of their written comment to the IACC during the meeting. For those interested in that opportunity, please indicate ''Interested in providing oral comment'' in your written submission, along with your name, address, email address, phone number, and professional/organizational affiliation so that ONAC staff can contact you if a slot is available.

For any given meeting, priority for comment slots will be given to individuals and organizations that have not previously provided comments in the current calendar year. This will help ensure that as many individuals and organizations as possible have an opportunity to share comments. Commenters going over their allotted 3-minute slot may be asked to conclude immediately in order to allow other comments and the rest of the meeting to proceed on schedule.

Public comment submissions received by 5:00 p.m. ET on Tuesday, January 9, 2024, will be provided to the Committee prior to the meeting for their consideration. Any written comments received after 5:00 p.m. ET, Tuesday, January 9, 2024, may be provided to the IACC either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. The IACC is not able to respond individually to comments. All public comments become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided. For public comment guidelines, see: *https://iacc.hhs.gov/meetings/public-comments/guidelines/.*

Technical issues: If you experience any technical problems with the videocast, please email *IACCPublicInquiries@mail.nih.gov.*

Disability Accommodations: All IACC Full Committee Meetings provide Closed Captioning through the NIH Videocasting website. Individuals whose full participation in the meeting will require special accommodations (*e.g.,* sign language or interpreting services, etc.) must submit a request to the Contact Person listed on the notice at least seven (7) business days prior to the meeting. Such requests should include a detailed description of the accommodation needed and a way for the IACC to contact the requester if more information is needed to fill the request. Special requests should be made at least seven (7) business days prior to the meeting; last-minute requests may be made but may not be possible to accommodate.

Security: In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-*

information/campus-access-security for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Pre-registration is recommended. Seats will be on a first come, first served basis, with expedited check-in for those who are pre-registered.

Meeting schedule subject to change.

More Information: Information about the IACC is available on the website: *http://www.iacc.hhs.gov.*

Dated: November 3, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24705 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of 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 Allergy and Infectious Diseases Special Emphasis Panel; Limited Competition: Collaborative Partnership to Advance Global Health Research (U01 Clinical Trial Not Allowed).

Date: November 29, 2023.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G62, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Eleazar Cohen, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G62, Rockville, MD 20892, (240) 669–5081, *ecohen@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24633 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The intramural programs and projects as well as the grant applications and/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: January 29–30, 2024.

Open: January 29, 2024, 12:00 p.m. to 5:00 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion of NIMH programs.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Closed: January 30, 2024, 10:30 a.m. to 12:00 p.m.

Agenda: Presentation of MHBSC Report.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Closed: January 30, 2024, 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Tracy Lynn Waldeck, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, DHHS, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (301) 480–6833, *tracy.waldeck@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 3, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24700 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Clinical Research Operations and Management Support (CROMS).

Date: December 7, 2023.

Time: 10:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Shilpakala Ketha, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52A, Rockville, MD 20852, (301) 761–6821, *shilpa.ketha@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24630 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2023–0672]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0031

AGENCY: Coast Guard, DHS.

ACTION: Sixty-Day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0031, Plan Approval and Records for Electrical Engineering Regulations; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before January 8, 2024.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2023–0672] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2023–0672], and must be received by January 8, 2024.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Plan Approval and Records for Electrical Engineering Regulations—Title 46 CFR Subchapter J.

OMB Control Number: 1625–0031.

Summary: The information is needed to ensure compliance with our rules on electrical engineering for the design and construction of U.S.-flag commercial vessels.

Need: Title 46 U.S.C. 3306 and 3703 authorize the Coast Guard to establish rules to promote the safety of life and property in commercial vessels. The electrical engineering rules appear at 46 CFR subchapter J (parts 110 through 113).

Forms: None.

Respondents: Owners, operators, shipyards, designers, and manufacturers of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 6,536 hours to 4,662 hours a year, due to an estimated decrease in the annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 26, 2023.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2023–24673 Filed 11–7–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

2024 Trade Facilitation and Cargo Security Summit

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of 2024 Trade Facilitation and Cargo Security Summit.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) will convene the 2024 Trade Facilitation and Cargo Security (TFCS) Summit in Philadelphia, PA, on March 26–28, 2024. The 2024 TFCS Summit will be open for the public to attend in person or via webinar. The 2024 TFCS Summit will feature CBP personnel, members of the trade community, and members of other government agencies in panel discussions on CBP's role in international trade initiatives and programs. Members of the international trade and transportation communities and other interested parties are encouraged to attend.

DATES: Tuesday, March 26, 2024 (opening remarks and general sessions, 8 a.m.–5 p.m. EDT), Wednesday, March 27, 2024 (breakout sessions, 8 a.m.–5 p.m. EDT), and Thursday, March 28, 2024 (breakout sessions, 8 a.m.–12 p.m. EDT).

ADDRESSES: The 2024 Trade Facilitation and Cargo Security Summit will be held at the Philadelphia Marriott Downtown at 1201 Market Street, Philadelphia, PA 19107. Directional signage will be displayed throughout the event space for registration, the sessions, and the exhibits.

Registration: Registration will open January 10, 2024 at 12 p.m. EST and close March 14, 2024 at 4 p.m. EDT. Registration information, including registration links when available, may be found on the event web page at *https://www.cbp.gov/trade/stakeholder-engagement/trade-facilitation-and-cargo-security-summit.* All registrations must be made online and will be confirmed with payment by credit card only. The registration fee to attend in person is $345.00 per person. The registration fee to attend via webinar is $28.00. Interested parties are requested to register immediately as space is limited. Members of the public who are pre-registered to attend and later need to cancel, may do so by using the link from their confirmation email or sending an email to *TFCSSummit@cbp.dhs.gov.* Please include your name and confirmation number with your cancellation request. Cancellation requests made after Friday, March 1, 2024, will not receive a refund.

FOR FURTHER INFORMATION CONTACT: Mrs. Daisy Castro, Office of Trade Relations, U.S. Customs and Border Protection at (202) 344–1440 or at *TFCSSummit@cbp.dhs.gov.* The most current 2024 TFCS Summit information can be found at *https://www.cbp.gov/trade/stakeholder-engagement/trade-facilitation-and-cargo-security-summit.*

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, please contact Mrs. Daisy Castro, Office of Trade Relations, U.S. Customs and Border Protection at (202) 344–1440 or at *TFCSSummit@cbp.dhs.gov,* as soon as possible.

SUPPLEMENTARY INFORMATION: This document announces that U.S. Customs and Border Protection (CBP) will convene the 2024 Trade Facilitation and Cargo Security (TFCS) Summit in Philadelphia, PA on March 26–28, 2024. The format of the 2024 TFCS Summit will consist of general sessions on the first day and breakout sessions on the second and third days. The 2024 TFCS Summit will feature panels composed of CBP personnel, members of the trade community, and members of other government agencies. The panel discussions will address the Customs Trade Partnership Against Terrorism (CTPAT), the Uyghur Forced Labor Prevention Act (UFLPA), the 21st Century Customs Framework (21CCF), the Automated Commercial Environment (ACE) 2.0, and other topics of interest to the trade community. The 2024 TFCS Summit agenda can be found on the CBP website: *https://www.cbp.gov/trade/stakeholder-engagement/trade-facilitation-and-cargo-security-summit.*

Hotel accommodations have been made available at the Philadelphia Marriott Downtown at 1201 Market Street, Philadelphia, PA 19107. Hotel room block reservation information can be found on the event web page at *https://www.cbp.gov/trade/stakeholder-engagement/trade-facilitation-and-cargo-security-summit.*

Felicia M. Pullam,

Executive Director, Office of Trade Relations.

[FR Doc. 2023–23135 Filed 11–7–23; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7070–N–82]

60-Day Notice of Proposed Information Collection; Housing Counseling Homeownership Initiative Notice of Funding Opportunity (HI NOFO); OMB Control No.: 2502–NEW

AGENCY: Office of Policy Development and Research, Chief Data 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 an additional 30 days of public comment.

DATES: *Comments Due Date:* December 8, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Clearance Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; 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;* telephone number (202) 402–3400. 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. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on August 30, 2023 at 88 FR 59935.

A. Overview of Information Collection

Title of Information Collection: Housing Counseling Homeownership Initiative Notice of Funding Opportunity (HI NOFO).

OMB Approval Number: 2502–NEW.

OMB Expiration Date: None.

Type of Request: New collection.

Form Numbers: HUD–91045; HUD–424–B; HUD–50153; HUD–2880; SF–LLL; SF–424

Description of the need for the information and proposed use: The HUD Office of Housing Counseling will use the information collected to objectively evaluate grant applicants on how well they will be able to meet the selection factors set forth in the new Homeownership Initiative Notice of Funding Opportunity, hereinafter HI–NOFO, based on their history of performance and on their responses to questions. The collection will also serve to monitor selected applicants or grantees to assess compliance and effectiveness. This collection of information is required for the award of the HI NOFO grant program in furtherance of HUD's mission to increase homeownership rates among historically underserved communities. The grant program looks to deliver measurable outcomes by awarding funds to HUD-approved Intermediaries, Multi-State Organizations, and State and Local government Housing Finance Agencies who have demonstrated experience providing culturally sensitive, linguistically appropriate pre- and post-purchase housing counseling. Selected agencies will provide independent, expert, and customized guidance to help underserved communities. The NOFO specific information is collected via the new form HUD–90145 (Homeownership Initiative Chart). All other forms that are part of this collection are mandatory OMB or HUD standard grant application forms.

This review is necessary to support HUD participating agencies who are seeking to increase the homeownership rate among historically underserved communities and stop or reverse the increasing homeownership gap resulting from the effects of the COVID–19 pandemic and resulting shortage of affordable homes within those communities. These agencies will provide targeted counseling, outreach to members of their communities as well as seek partnerships with other agencies to help individuals and families achieve sustainable homeownership, no matter their race, ethnicity, disability status, or other protected class.

Respondents: HUD-approved non-profit HUD National and Regional Intermediaries (Intermediaries), Multi-State Organizations (MSOs), and State Housing Finance Agencies (SHFAs).

Estimated Number of Respondents: 56.

Estimated Number of Responses: 341.

Frequency of Response: Annually.

Average Hours per Response: 8.7.

Total Estimated Burden: 2,968 hours.

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 respondents, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).

Colette Pollard,

Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2023–24665 Filed 11–7–23; 8:45 am]

BILLING CODE 4210–67–P

INTER-AMERICAN FOUNDATION

Submission for OMB Review; Comments Request

AGENCY: Inter-American Foundation.

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the provisions of the Paperwork Reduction Act, agencies are required to publish a Notice in the **Federal Register** notifying the public that the agency is creating a new information collection for OMB review and approval and requests public review and comment on the submission. The agencies received no comments in response to the sixty (60) day notice. Comments are being solicited on the need for the information; the accuracy of the burden estimate; the quality, practical utility, and clarity of the information to be collected; and ways to minimize reporting the burden, including automated collected techniques and uses of other forms of technology.

DATES: Comments must be received by December 8, 2023.

ADDRESSES: Comments and requests for copies of the subject information collection may be sent by any of the following methods:

- *Mail:* Nicole Stinson, Associate General Counsel, Inter-American Foundation, 1331 Pennsylvania Ave. NW, Suite 1200 North, Washington, DC 20004.
- *Email: nstinson@iaf.gov*.

Instructions: All submissions received must include the agency name and agency form name or OMB control number for this information collection. Electronic submissions must include the agency form name in the subject line to ensure proper routing. Please note that all written comments received in response to this notice will be considered public records.

FOR FURTHER INFORMATION CONTACT: Associate General Counsel: Nicole Stinson, (202) 683–7117.

SUPPLEMENTARY INFORMATION: The agency received no comments in response to the sixty (60) day notice published in **Federal Register** volume 88 page 54644 on August 11, 2023. Upon publication of this notice, IAF will submit to OMB a request for approval of the following information collections.

Summary Form Under Review

Title of Collection: Grant Management System Registration, IAF–01.

Type of Review: New information collection.

OMB Control Number: Not assigned, new information collection.

Type of Respondent/Affected Public: Private Sector, Businesses or other for profits, Not-for-profit institutions.

Frequency: Once.

Estimated Number of Respondents per Year: 1,400.

Estimated Time per Respondent: 0.1 hours.

Estimated Total Annual Burden Hours: 140 hours.

Abstract: The IAF works to promote sustainable development in Latin America and the Caribbean by directly supporting qualified civil society organizations through funding actions, such as grants and cooperative agreements. This collection will allow grant seekers to register for a new online IAF grant portal if they meet basic eligibility requirements. Transition to an online portal will allow electronic grant application and reporting which will increase the efficiency of IAF's grant management program.

Summary Form Under Review

Title of Collection: Grant Application, IAF–02.

Type of Review: New information collection.

OMB Control Number: Not assigned, new information collection.

Type of Respondent/Affected Public: Private Sector, Businesses or other for profits, Not-for-profit institutions.

Frequency: Once.

Estimated Number of Respondents per Year: 1,400.

Estimated Time per Respondent: 14 hours.

Estimated Total Annual Burden Hours: 19,600 hours.

Abstract: The IAF works to promote sustainable development in Latin America and the Caribbean by directly supporting qualified civil society organizations through funding actions, such as grants and cooperative agreements. This collection will gather application information directly from grant seekers including details about the applicant's organization, the development opportunity, and proposed project activities. Using this information, IAF is able to perform an initial assessment of the proposed project and determine which applicants are qualified as well as which projects are best positioned to advance grassroots development in the region. The IAF has made an effort to standardize the basic level of information required for this review in order to reduce the burden on both applicants and IAF staff reviewing the applications.

Summary Form Under Review

Title of Collection: Grant Programmatic and Financial Reporting, IAF–03.

Type of Review: New information collection.

OMB Control Number: Not assigned, new information collection.

Type of Respondent/Affected Public: Private Sector, Businesses or other for profits, Not-for-profit institutions.

Frequency: Twice a year.

Estimated Number of Respondents per year: 450.

Estimated Time per Respondent: 18 hours.

Estimated Total Annual Burden Hours: 16,200 hours.

Abstract: The IAF works to promote sustainable development in Latin America and the Caribbean by directly supporting qualified civil society organizations through funding actions, such as grants and cooperative agreements. In order to track grant progress toward desired results and ensure compliance with the terms and conditions of the agreement, the IAF seeks to establish a requirement that grantees provide programmatic and financial information every six months during the grant period, including reporting on project indicators, narrative data on grant achievements and challenges, and a record of spent funds.

This information is necessary as it allows IAF to ensure that the grantee is using project funds responsibly and making the necessary strides toward achieving the results laid out in the grant agreement.

Dated: November 3, 2023.

Nicole Stinson,

Associate General Counsel, Office of the General Counsel.

[FR Doc. 2023–24710 Filed 11–7–23; 8:45 am]

BILLING CODE 7025–01–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–921 (Fourth Review)]

Folding Gift Boxes From China; 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 folding gift boxes from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on June 1, 2023 (88 FR 35917) and determined on September 5, 2023, that it would conduct an expedited review (88 FR 67813, October 2, 2023).

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 November 3, 2023. The views of the Commission are contained in USITC Publication 5471 (November 2023), entitled *Folding Gift Boxes from China: Investigation No. 731–TA–921 (Fourth Review).*

By order of the Commission.

Issued: November 3, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–24703 Filed 11–7–23; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

INTERNATIONAL TRADE COMMISSION

[USITC SE–23–054]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 17, 2023 at 11 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Commission vote on Inv. Nos 701–TA–695–698 and 731–TA–1643–1657 (Preliminary) (Aluminum Extrusions from China, Colombia, Dominican Republic, Ecuador, India, Indonesia, Italy, Malaysia, Mexico, South Korea, Taiwan, Thailand, Turkey, United Arab Emirates, and Vietnam). The Commission currently is scheduled to complete and file its determinations on November 20, 2023; views of the Commission currently are scheduled to be completed and filed on November 28, 2023.
5. Outstanding action jackets: none.

CONTACT PERSON FOR MORE INFORMATION: Sharon Bellamy, Supervisory Hearings and Information Officer, 202–205–2000.

The Commission is holding the meeting under the Government in the

Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 6, 2023.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2023–24812 Filed 11–6–23; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1287]

Importer of Controlled Substances Application: Noramco

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Noramco has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before December 8, 2023. Such persons may also file a written request for a hearing on the application on or before December 8, 2023.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on October 4, 2023, Noramco, 500 Swedes Landing Road, Wilmington, Delaware 19801–4417, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Nabilone	7379	II
Phenylacetone	8501	II
Opium, Raw	9600	II
Opium Extracts	9610	II
Opium Fluid Extract	9620	II
Opium Tincture	9630	II
Opium Powdered	9639	II
Opium Granulated	9640	II
Opium Poppy/Poppy Straw.	9650	II
Noroxymorphone	9668	II
Poppy Straw Concentrate.	9670	II
Tapentadol	9780	II

The company plans to import Phenylacetone (8501), and Poppy Straw Concentrate (9670) to bulk manufacture other controlled substances for distribution to its customers. The company plans to import an intermediate form of Tapentadol (9780) to bulk manufacture Tapentadol for distribution to its customers. In reference to drug codes 7360 (Marihuana) and 7370 (Tetrahydrocannabinols), the company plans to import a synthetic cannabidiol and a synthetic Tetrahydrocannabinol. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Claude Redd,

Acting Deputy Assistant Administrator.

[FR Doc. 2023–24614 Filed 11–7–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1286]

Bulk Manufacturer of Controlled Substances Application: Noramco

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Noramco has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before January 8, 2024. Such persons may also file a written request for a hearing on the application on or before January 8, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on October 04, 2023, Noramco, 500 Swedes Landing Road, Wilmington, Delaware 19801–4417, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Codeine-N-oxide	9053	I
Dihydromorphine	9145	I
Hydromorphinol	9301	I
Morphine-N-oxide	9307	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II

Controlled substance	Drug code	Schedule
Nabilone	7379	II
Phenylacetone	8501	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium extracts	9610	II
Opium fluid extract	9620	II
Opium, tincture	9630	II
Opium, powdered	9639	II
Opium, granulated	9640	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Tapentadol	9780	II

The company plans to bulk manufacture the listed controlled substances as an Active Pharmaceutical Ingredient for supply to its customers. In reference to drug codes 7360 (Marihuana), and 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

Claude Redd,

Acting Deputy Assistant Administrator.

[FR Doc. 2023–24613 Filed 11–7–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1291]

Bulk Manufacturer of Controlled Substances Application: Curia Missouri, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Curia Missouri Inc. has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before January 8, 2024. Such persons may also file a written request for a hearing on the application on or before January 8, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on August 3, 2023, Curia Missouri Inc., 2460 West Bennett Street, Springfield, Missouri 65807–1229, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Phenylacetone	8501	II
Tapentadol	9780	II

The company plans to bulk manufacture the listed controlled substances for internal use intermediates or for sale to its customers. No other activities for these drug codes are authorized for this registration.

Claude Redd,

Acting Deputy Assistant Administrator.

[FR Doc. 2023–24615 Filed 11–7–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

220th Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 220th open meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans (also known as the ERISA Advisory Council) will be held on December 11–12, 2023.

On Monday, December 11, 2023, the meeting will begin at 1:00 p.m. and end at approximately 4:30 p.m. (ET). On Tuesday, December 12, 2023, the meeting will begin at 8:30 a.m. and end at approximately 3:00 p.m. (ET), with a break for lunch.

The meeting will take place at the U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210 in Room 6, C5320. The meeting will also be accessible via videoconference and some participants, as well as members of the public, may elect to attend virtually. Instructions for public videoconference access will be available on the ERISA Advisory Council's web page at *https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/erisa-advisory-council* approximately one week prior to the meeting.

The purpose of the open meeting is for Advisory Council members to finalize their observations and recommendations on the issues they studied in 2023, present their observations and recommendations to the Department of Labor, and receive an update from leadership of the Employee Benefits Security Administration (EBSA).

The issues studied by the ERISA Advisory Council in 2023 are: (1) Long-Term Disability Benefits and Mental Health Disparity, and (2) Recordkeeping in the Electronic Age. Descriptions of these topics are available on the ERISA Advisory Council's web page at *https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/erisa-advisory-council.*

Organizations or members of the public wishing to submit a written statement may do so on or before Monday, December 4, 2023, to Christine Donahue, Executive Secretary, ERISA Advisory Council. Statements should be transmitted electronically as an email attachment in text or pdf format to *donahue.christine@dol.gov.* Statements transmitted electronically that are included in the body of the email will not be accepted. Relevant statements received on or before Monday, December 4, 2023, will be included in the record of the meeting and made available through the EBSA Public Disclosure Room. No deletions, modifications, or redactions will be made to the statements received as they are public records. *Warning:* Do not include any personally identifiable or confidential business information that you do not want publicly disclosed.

Individuals or representatives of organizations interested in addressing the ERISA Advisory Council at the public meeting must submit a written request to the Executive Secretary on or before Monday, December 4, 2023, via email to *donahue.christine@dol.gov.*

Requests to address the Council must include: (1) the name, title, organization, address, email address, and telephone number of the individual who would appear; (2) if applicable, the name of the organization(s) whose views would be represented; and (3) a concise summary of the statement that would be presented. If permitted, oral presentations will be limited to ten minutes, but an extended statement may be submitted for the record.

Individuals who need special accommodations should contact the Executive Secretary on or before Monday, December 4, 2023, via email to *donahue.christine@dol.gov* or by telephoning (202) 693–8641.

For more information about the meeting, contact the Executive Secretary at the address or telephone number above.

Signed at Washington, DC, this 2nd day of November, 2023.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. 2023–24657 Filed 11–7–23; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of National Council on the Humanities

AGENCY: National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the National Council on the Humanities will meet to advise the Chair of the National Endowment for the Humanities (NEH) with respect to policies, programs and procedures for carrying out her functions; to review applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965 and make recommendations thereon to the Chair; and to consider gifts offered to NEH and make recommendations thereon to the Chair.

DATES: The meeting will be held on Thursday, November 16, 2023, from 10:00 a.m. until 2:30 p.m., and Friday, November 17, 2023, from 10:00 a.m. until adjourned.

ADDRESSES: The meeting will be held by videoconference originating at Constitution Center, 400 7th Street SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, 4th Floor, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: The National Council on the Humanities is meeting pursuant to the National Foundation on the Arts and Humanities Act of 1965 (20 U.S.C. 951–960, as amended).

The National Council will convene in executive session by videoconference on November 16, 2023, from 10:00 a.m. until 11:00 a.m.

The following Committees of the National Council on the Humanities will convene by videoconference on November 16, 2023, from 11:00 a.m. until 2:30 p.m., to discuss specific grant applications and programs before the Council: Challenge Programs; Digital Humanities; Education Programs; Federal/State Partnership; Preservation and Access; Public Programs; and Research Programs.

The National Council will convene in executive session by videoconference on November 17, 2023, from 10:00 a.m. until 11:00 a.m.

The plenary session of the National Council on the Humanities will then convene by videoconference on November 17, 2023, at 11:00 a.m. The agenda for the plenary session will be as follows:

A. Minutes of Previous Meeting
B. Reports
   1. Chair's Remarks
   2. Senior Deputy Chair's Remarks
   3. Congressional Affairs Report
   4. Actions on Requests for Chair's Grants and Supplemental Funding
   5. Actions on Previously Considered Applications
C. Challenge Programs
D. Digital Humanities
E. Education Programs
F. Federal/State Partnership
G. Preservation and Access
H. Public Programs
I. Research Programs

This meeting of the National Council on the Humanities will be closed to the public pursuant to sections 552b(c)(4), 552b(c)(6), and 552b(c)(9)(B) of Title 5 U.S.C., as amended, because it will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, and discussion of certain information, the premature disclosure of which could significantly frustrate implementation of proposed agency action. I have made this determination pursuant to the authority granted me by the Chair's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: November 3, 2023.

Jessica Graves,

Paralegal Specialist, National Endowment for the Humanities.

[FR Doc. 2023–24699 Filed 11–7–23; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL LABOR RELATIONS BOARD

Notice of Appointments of Individuals To Serve as Members of Performance Review Boards

AGENCY: National Labor Relations Board.

ACTION: Notice; appointment to serve as members of performance review boards.

SUMMARY: The National Labor Relations Board is issuing this notice that the individuals whose names and position titles appear below have been appointed to serve as members of performance review boards in the National Labor Relations Board for the rating year beginning October 1, 2022 and ending September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Roxanne L. Rothschild, Executive Secretary, National Labor Relations Board, 1015 Half Street SE, Washington, DC 20570, (202) 273–1940 (this is not a toll-free number), 1–866–315–6572 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

Name and Title

Andrew Krafts—Executive Assistant to the Chairman (Chief of Staff), Office of the Chairman

Grant Kraus—Deputy Chief Counsel, Office of the Chairman

Terence G. Schoone-Jongen—Director, Office of Representation Appeals

Peter Sung Ohr—Deputy General Counsel, Office of the General Counsel

Joan A. Sullivan—Associate General Counsel, Division of Operations Management

Nancy Kessler Platt (Alternate)—Associate General Counsel, Division of Legal Counsel

Authority: 5 U.S.C. 4314(c)(4).

By Direction of the Board.

Dated: November 3, 2023.

Roxanne L. Rothschild,

Executive Secretary.

[FR Doc. 2023–24675 Filed 11–7–23; 8:45 am]

BILLING CODE 7545–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–302; NRC–2023–0174]

Accelerated Decommissioning Partners Crystal River Unit 3, LLC; Crystal River Unit 3 Nuclear Generating Plant; License Termination Plan

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of receipt; public meeting, and request for comment.

SUMMARY: On December 12, 2022, as supplemented on June 9, 2023, the U.S. Nuclear Regulatory Commission (NRC) received from Accelerated Decommissioning Partners Crystal River Unit 3, LLC (ADP CR3, licensee) a license amendment request to add a license condition to include the requirements of a License Termination Plan (LTP) for the Crystal River Unit 3 Nuclear Generating Plant (CR3). The LTP provides details about the known radiological information for the site, the planned demolition and decommissioning tasks to be completed, and the final radiological surveys and data that must be obtained for termination of the NRC's license for CR3. The NRC is requesting public comments on CR3's LTP and will hold a public meeting to discuss the LTP.

DATES: Submit comments by March 7, 2024. Comments received after this date will be considered, if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. The public meeting will be held on Thursday, December 7, 2023, from 5 p.m. until 8 p.m. eastern time (ET), at the Citrus County Chamber of Commerce, located at 915 N Suncoast Blvd., in Crystal River, Florida. The public meeting is also accessible through an online webinar. See Section IV, ''Request for Comment and Public Meeting,'' of this document for additional information.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0174. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the ''For Further Information Contact'' section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Timothy J. Barvitskie, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–2480; email: *Timothy.Barvitskie@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0174 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0174.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. ET, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0174 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

Accelerated Decommissioning Partners Crystal River Unit 3, LLC (ADP CR3, licensee) is currently the licensed operator responsible for decommissioning of Crystal River Unit 3 Nuclear Generating Plant (CR3). Prior to ADP CR3, Duke Energy Florida (DEF) held the licensed authority for CR3. The Facility Operating License No. DPR–72, provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect. The facility is a pressurized water reactor located in Citrus County, Florida.

By letter dated February 20, 2013, pursuant to paragraphs 50.82(a)(1)(i)–(ii) of title 10 of the *Code of Federal Regulations* (10 CFR), DEF formally notified the NRC that it had determined to permanently cease power operations at CR3 and that it had permanently removed fuel from the reactor vessel. In this letter, DEF explained that CR3 had been safely shutdown since September 26, 2009, and that all fuel had been permanently removed from the CR3 reactor vessel as of May 28, 2011. DEF then placed the fuel in the CR3 spent fuel pool for temporary storage. After removing the fuel in 2011, DEF stated that it had determined it would retire CR3.

DEF submitted its Post-Shutdown Decommissioning Activities Report (PSDAR) on December 2, 2013. The PSDAR described DEF's proposed decommissioning activities and schedule. At that time, DEF decided to place the facility in long-term storage (*i.e.,* the SAFSTOR decommissioning option) as described in the PSDAR. SAFSTOR is a method of

decommissioning in which a nuclear facility is placed and maintained in a condition that allows the facility to be safely stored and subsequently decontaminated (deferred decontamination) to levels that permit release for unrestricted use. DEF planned to continue in SAFSTOR until 2067.

By letter dated June 14, 2019, as supplemented by letters dated January 17, 2020, and March 5, 2020, DEF and ADP CR3 requested that the NRC consent to the proposed direct transfer of licensed authority under CR3 Facility Operating License No. DPR–72 from DEF to ADP CR3. By letter dated June 26, 2019, ADP CR3 submitted a revised PSDAR contingent upon the transfer of the CR3 license authority to ADP CR3 pursuant to the terms of the Decommissioning Services Agreement between DEF and ADP CR3. ADP CR3 is a joint venture between NorthStar Group Services and Orano USA. The revised PSDAR changed the decommissioning approach for CR3 from SAFSTOR to the immediate decontamination and dismantlement of the facility (*i.e.,* the DECON decommissioning option). DECON is a method of decommissioning in which structures, systems, and components that contain radioactive contamination are actively removed from the site and safely disposed of at a commercially operated low-level waste disposal facility or decontaminated to a level that permits the site to be released for unrestricted use as soon as possible after removal of the spent fuel from the spent fuel pool.

By Order dated April 1, 2020, the NRC provided its consent to the direct transfer of licensed authority. On October 1, 2020, the licensed authority was transferred from DEF to ADP CR3 pursuant to the terms of the Decommissioning Services Agreement between DEF and ADP CR3. Per the agreement, DEF remains the NRC-licensed owner of the plant, property, and decommissioning trust fund but not the spent fuel. ADP CR3 became the NRC-licensed operator responsible for decommissioning and maintaining the Independent Spent Fuel Storage Installation (ISFSI) under a service agreement with ADP SF1, and ADP SF1 became the owner of the spent nuclear fuel, high-level waste, and Greater-Than-Class C waste stored in the ISFSI.

On December 12, 2022, ADP CR3 submitted its LTP to the NRC as supplemented by letter dated June 9, 2023. Paragraph 50.82(a)(9), ''Termination of license,'' specifies that an application for license termination must be accompanied or preceded by a LTP, which is subject to NRC review and approval. The LTP addresses site characterization to ensure that the scope of final status surveys (FSS) of the site cover all areas where contamination existed, remains, or has the potential to exist or remain, identification of remaining dismantlement activities, plans for site remediation, a description of the FSS plans to confirm that CR3 will meet the release criteria in 10 CFR part 20, subpart E, ''Radiological Criteria for License Termination,'' dose-modeling scenarios that ensure compliance with the radiological criteria for license termination, an estimate of the remaining site-specific decommissioning costs and an updated assessment of the environmental effects of decommissioning CR3. Once approved, the LTP would become a supplement to the CR3 Defueled Safety Analysis Report.

According to 10 CFR 50.82(a)(9)(iii), after the licensee submits an LTP the NRC must hold a public meeting near the site. The purpose of the meeting is for the NRC staff to discuss the NRC's review of the LTP and to request public comments on the LTP. In addition, in accordance with 10 CFR 50.82(a)(9)(iii) and 20.1405, upon the receipt of an LTP from a licensee, NRC must publish a notice in the **Federal Register** and solicit comments from affected parties.

III. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document description	ADAMs accession number
DEF notification of its intent to permanently cease operations at Crystal River Unit 3, dated February 20, 2013.	ML13056A005.
DEF submittal of PSDAR for Crystal River Unit 3, dated December 2, 2013	ML13340A009.
DEF submittal of updated PSDAR for Crystal River Unit 3 to reflect the change from SAFSTOR to DECON, dated June 26, 2019.	ML19177A080.
DEF and ADP CR3 proposed direct transfer of CR3 Facility Operating License No. DPR–72 from DEF to ADP CR3 dated June 14, 2019, and supplemented on January 17, 2020, and March 5, 2020.	ML19170A209 (Package). ML20017A216. ML20065K737.
NRC Order providing consent to the direct license direct transfer of CR3 Facility Operating License No. DPR–72 from DEF to ADP CR3, dated April 1, 2020.	ML20069A028 (Package).
ADP CR3 submittal of their LTP to the NRC, dated December 12, 2022	ML22355A441.
ADP CR3 supplement to the LTP, dated June 9, 2023	ML23180A051 (Package).

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2023–0174. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2023–0174); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link.

IV. Request for Comment and Public Meeting

The NRC is requesting public comments on the CR3 LTP. The NRC will conduct a public meeting to discuss the LTP and receive comments on Thursday, December 7, 2023, from 5 p.m. until 8 p.m. ET, at the Citrus County Chamber of Commerce, located at 915 N Suncoast Blvd., in Crystal River, Florida. Please contact Mr. Timothy Barvitskie no later than Tuesday, December 5, 2023, if accommodations or special equipment is needed for you to attend or to provide comments, so that the NRC staff can determine whether the request can be accommodated. For additional information regarding the meeting, see the NRC's Public Meeting Schedule website at *https://meetings.nrc.gov/pmns/mtg.* The agenda will be posted no later than 10 days prior to the meeting.

Dated: November 2, 2023.

For the Nuclear Regulatory Commission.

Marlayna V. Doell,

Acting Chief, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2023–24620 Filed 11–7–23; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–18, 50–70, 50–73, 50–183, and 70–754; NRC–2023–0191]

Vallecitos Nuclear Center; Consideration of Approval of Transfer of Licenses and Conforming Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Application for direct transfer of licenses; opportunity to comment, request a hearing, and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC, the Commission) received and is considering approval of an application filed by GE-Hitachi Nuclear Energy Americas, LLC (GEHA) and NorthStar Vallecitos, LLC (NorthStar Vallecitos) on September 1, 2023, as supplemented by letters dated September 5, 2023, October 19, 2023, and November 1, 2023. The application seeks NRC approval of the direct transfer of NRC license numbers DPR–1, TR–1, R–33, DR–10, and SNM–960 for the Vallecitos Nuclear Center from the current holder, GEHA, to NorthStar Vallecitos. The NRC is also considering amending the licenses for administrative purposes to reflect the proposed transfer. The application contains sensitive unclassified non-safeguards information (SUNSI).

DATES: Submit comments by December 8, 2023. A request for a hearing or petition for leave to intervene must be filed by November 28, 2023. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must follow the instructions in section VI of the **SUPPLEMENTARY INFORMATION** section of this notice.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0191. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Hearing.Docket@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time (ET) Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Chris Allen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6877; email: *William.Allen@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0191 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0191.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The application is available in ADAMS under Accession Nos. ML23244A247, ML23248A232, ML23292A336, and ML23305A052.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. ET, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0191 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering the issuance of an order under 10 CFR 50.80 and 10 CFR 70.36 approving the direct transfer of control of NRC license numbers DPR–1, TR–1, R–33, DR–10, and SNM–960 for the Vallecitos Nuclear Center that are currently held by GEHA. The licenses would be transferred to NorthStar Vallecitos. The NRC is also considering amending the licenses for administrative purposes to reflect the proposed transfer.

Following approval of the proposed direct transfer of control of the licenses, NorthStar Vallecitos would acquire ownership of the Vallecitos Nuclear Center. No physical changes to the Vallecitos Nuclear Center are being proposed in the application. The application stated that, at the time of the transfer to NorthStar Vallecitos, none of the licenses will authorize reactor operation. Since NRC license number R–33 is currently authorized to operate, the application requested that the NRC condition any order authorizing the transfer such that the transfer may not

close before license number R–33 no longer authorizes reactor operation.

The NRC's regulations at 10 CFR 50.80 and 10 CFR 70.36 state that no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. The Commission will approve an application for the direct transfer of a license if the Commission determines that the proposed transferee is qualified to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission.

Before issuance of the proposed conforming license amendments, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations. As provided in 10 CFR 2.1315, unless otherwise determined by the Commission with regard to a specific application, the Commission has determined that any amendment to the license of a utilization facility which does no more than conform the license to reflect the transfer action involves no significant hazards consideration. No contrary determination has been made with respect to this specific license amendment application. In light of the generic determination reflected in 10 CFR 2.1315, no public comments with respect to significant hazards considerations are being solicited, notwithstanding the general comment procedures contained in 10 CFR 50.91.

III. Opportunity To Comment

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted as described in the **ADDRESSES** section of this document.

IV. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 20 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 20 days from the date of publication of this notice in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 20 days from the date of publication of this notice. Alternatively, a State, local governmental body, federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (*https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053*) and on the NRC's public website at *https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate.*

V. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, federally-recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056) and on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html.*

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an

exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

For further details with respect to this application, see the application dated September 1, 2023 (ADAMS Accession No. ML23244A247), as supplemented by letters dated September 5, 2023 (ADAMS Accession No. ML23248A232), October 19, 2023 (ADAMS Accession No. ML23292A336), and November 1, 2023 (ADAMS Accession No. ML23305A052).

VI. Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Any person who desires access to proprietary, confidential commercial information that has been redacted from the application should contact the applicant by contacting Michelle Catts at *Michelle.Catts@GE.com* for the purpose of negotiating a confidentiality agreement or a proposed protective order with the applicant. If no agreement can be reached, persons who desire access to this information may file a motion with the Secretary and addressed to the Commission that requests the issuance of a protective order.

Dated: November 2, 2023.

For the Nuclear Regulatory Commission.

Marlayna V. Doell,

Acting Chief, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2023–24651 Filed 11–7–23; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–33 and CP2024–33; MC2024–34 and CP2024–34; MC2024–35 and CP2024–35; MC2024–36 and CP2024–36; MC2024–37 and CP2024–37]

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:* November 13, 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).:* MC2024–33 and CP2024–33; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 89 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 2, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:*

[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).

Jennaca D. Upperman; *Comments Due:* November 13, 2023.

2. *Docket No(s).:* MC2024–34 and CP2024–34; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 90 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 2, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* November 13, 2023.

3. *Docket No(s).:* MC2024–35 and CP2024–35; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 91 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 2, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* November 13, 2023.

4. *Docket No(s).:* MC2024–36 and CP2024–36; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 92 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 2, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* November 13, 2023.

5. *Docket No(s).:* MC2024–37 and CP2024–37; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 93 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 2, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* November 13, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–24684 Filed 11–7–23; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98846; File No. SR–CboeBZX–2023–087]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To List and Trade Shares of the Invesco Galaxy Ethereum ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

November 2, 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 October 20, 2023, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (''BZX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (''Commission'' or ''SEC'') a proposed rule change to list and trade shares of the Invesco Galaxy Ethereum ETF (the ''Trust''),[3] under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, 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 proposes to list and trade the Shares of the Invesco Galaxy Ethereum ETF [4] under BZX Rule 14.11(e)(4),[5] which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.[6]

According to the Registration Statement, the Trust is neither an investment company registered under the Investment Company Act of 1940, as amended,[7] nor a commodity pool for purposes of the Commodity Exchange Act (''CEA''), and neither the Trust nor the Sponsor is subject to regulation as a commodity pool operator or a commodity trading adviser in connection with the Shares.

Invesco Galaxy Ethereum ETF

Invesco Capital Management is the sponsor of the Trust (the ''Sponsor''). A well-established global fund administrator and transfer agent, Bank of New York Mellon (''BNYM'') will be the administrator (''Administrator'') and transfer agent (''Transfer Agent''). Coinbase Custody Trust Company, LLC (''ETH Custodian''), a third-party regulated custodian, will be responsible for custody of the Trust's Ether (''ETH''), and Bank of New York Mellon (the ''Cash Custodian'') will be responsible for custody of any Trust cash holdings. Delaware Trust Company is the trustee (''Trustee'').

According to the Registration Statement, each Share will represent a fractional undivided beneficial interest in the Trust. The Trust's assets will consist of ETH held by the Custodian on behalf of the Trust. The Trust generally does not intend to hold cash or cash

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Trust was formed as a Delaware statutory trust on September 27, 2023, and is operated as a grantor trust for U.S. federal tax purposes. The Trust has no fixed termination date.

[4] On September 29, 2023, the Trust filed with the Commission an initial registration statement (the ''Registration Statement'') on Form S–1 under the Securities Act of 1933 (15 U.S.C. 77a). The description of the operation of the Trust herein is based, in part, on the Registration Statement. The Registration Statement is not yet effective and the Shares will not trade on the Exchange until such time that the Registration Statement is effective.

[5] The Commission approved BZX Rule 14.11(e)(4) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[6] All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange.

[7] 15 U.S.C. 80a–1.

equivalents. However, there may be situations where the Trust will unexpectedly hold cash on a temporary basis.

When the Trust sells or redeems its Shares, it will do so in ''in-kind'' transactions in large blocks of Shares (a ''Creation Basket'') at the Trust's NAV. Authorized participants will deliver, or facilitate the delivery of, ETH to the Trust's account with the Custodian in exchange for Shares when they purchase Shares, and the Trust, through the Custodian, will deliver ETH to such authorized participants when they redeem Shares with the Trust. Authorized participants may then offer Shares to the public at prices that depend on various factors, including the supply and demand for Shares, the value of the Trust's assets, and market conditions at the time of a transaction. Shareholders who buy or sell Shares during the day from their broker may do so at a premium or discount relative to the NAV of the Shares of the Trust.

Background

Ethereum is free software that is hosted on computers distributed throughout the globe. It employs an array of logic, called a protocol, to create a unified understanding of ownership, commercial activity, and business logic. This allows users to engage in commerce without the need to trust any of its participants or counterparties. Ethereum code creates verifiable and unambiguous rules that assign clear, strong property rights to create a platform for unrestrained business formation and free exchange. It is widely understood that no single intermediary or entity operates or controls the Ethereum network (referred to as ''decentralization''), the transaction validation and recordkeeping infrastructure of which is collectively maintained by a disparate user base. The Ethereum network allows people to exchange tokens of value, or ETH, which are recorded on a distributed public recordkeeping system or ledger known as a blockchain (the ''Ethereum Blockchain''), and which can be used to pay for goods and services, including computational power on the Ethereum network, or converted to fiat currencies, such as the U.S. dollar, at rates determined on digital asset exchanges or in individual peer-to-peer transactions. Furthermore, by combining the recordkeeping system of the Ethereum Blockchain with a flexible scripting language that is programmable and can be used to implement sophisticated logic and execute a wide variety of instructions, the Ethereum network is intended to act as a foundational infrastructure layer on top of which users can build their own custom software programs, as an alternative to centralized web servers. In theory, anyone can build their own custom software programs on the Ethereum network. In this way, the Ethereum network represents a project to expand blockchain deployment beyond a limited-purpose, peer-to-peer private money system into a flexible, distributed alternative computing infrastructure that is available to all. On the Ethereum network, ETH is the unit of account that users pay for the computational resources consumed by running their programs.

Heretofore, U.S. retail investors have lacked a U.S. regulated, U.S. exchange-traded vehicle to gain exposure to ETH. Instead current options include: (i) facing the counter-party risk, legal uncertainty, technical risk, and complexity associated with accessing spot Ether or (ii) over-the-counter Ether funds (''OTC ETH Funds'') with high management fees and potentially volatile premiums and discounts;[8] Meanwhile, investors in other countries, including Germany, Switzerland and France, are able to use more traditional exchange listed and traded products (including exchange-traded funds holding physical ETH) to gain exposure to ETH. Investors across Europe have access to products which trade on regulated exchanges and provide exposure to a broad array of spot crypto assets. U.S. investors, by contrast, are left with fewer and more risky means of getting Ether exposure.[9]

To this point, the lack of an ETP that holds spot ETH (a ''Spot ETH ETP'') exposes U.S. investor assets to significant risk because investors that would otherwise seek cryptoasset exposure through a Spot ETH ETP are forced to find alternative exposure through generally riskier means. For example, investors in OTC ETH Funds are not afforded the benefits and protections of regulated Spot ETH ETPs, resulting in retail investors suffering losses due to drastic movements in the premium/discount of OTC ETH Funds. An investor who purchased the largest OTC ETH Fund in January 2021 and held the position at the end of 2022 would have suffered a 69% loss due to the premium/discount, even if the price of ETH did not change. Many retail investors likely suffered losses due to this premium/discount in OTC ETH Fund trading; all such losses could have been avoided if a Spot ETH ETP had been available. Additionally, many U.S. investors that held their digital assets in accounts at FTX,[10] Celsius Network LLC,[11] BlockFi Inc.[12] and Voyager Digital Holdings, Inc.[13] have become unsecured creditors in the insolvencies of those entities. If a Spot ETH ETP was available, it is likely that at least a portion of the billions of dollars tied up in those proceedings would still reside in the brokerage accounts of U.S. investors, having instead been invested in a transparent, regulated, and well-understood structure—a Spot ETH ETP. To this point, approval of a Spot ETH ETP would represent a major win for the protection of U.S. investors in the cryptoasset space. The Trust, like all other series of Commodity-Based Trust Shares, is designed to protect investors against the risk of losses through fraud and insolvency that arise by holding digital assets, including ETH, on centralized platforms.

Applicable Standard

The Commission has historically approved or disapproved exchange filings to list and trade series of Trust Issued Receipts, including spot-based Commodity-Based Trust Shares, on the basis of whether the listing exchange has in place a comprehensive surveillance sharing agreement with a regulated market of significant size related to the underlying commodity to

[8] The premium and discount for OTC ETH Funds is known to move rapidly. For example, over the period of 12/21/20 to 1/21/21, the premium for the largest OTC ETH Fund went from 238.63% to 5.1%. While the price of Ether appreciated significantly during this period and NAV per share increased by 101.40%, the price per share decreased by 37.49%. This means that investors are holding shares of a fund with roughly $4.8 billion in assets under management that experiences significant volatility in its premium and discount outside of the fluctuations in price of the underlying asset. Even operating within the normal premium and discount range, it's possible for an investor to buy shares of an OTC ETH Fund only to have those shares quickly lose 10% or more in dollar value excluding any movement of the price of ether. That is to say—the price of Ether could have stayed exactly the same from market close on one day to market open the next, yet the value of the shares held by the investor decreased only because of the fluctuation of the premium. As more investment vehicles, including mutual funds and ETFs, seek to gain exposure to ether, the easiest option for a buy and hold strategy for such vehicles is often an OTC ETH Fund, meaning that even investors that do not directly buy OTC ETH Funds can be disadvantaged by extreme premiums (or discounts) and premium volatility.

[9] The Exchange notes that the list of countries above is not exhaustive and that securities regulators in a number of additional countries have either approved or otherwise allowed the listing and trading of Spot ETH ETPs.

[10] *See* FTX Trading Ltd., et al., Case No. 22–11068.

[11] *See* Celsius Network LLC, et al., Case No. 22–10964.

[12] *See* BlockFi Inc., Case No. 22–19361.

[13] *See* Voyager Digital Holdings, Inc., et al., Case No. 22–10943.

be held.[14] With this in mind, the CME Ether Futures (''CME ETH Futures'') market, which launched in February 2021, is the proper market to consider in determining whether there is a related regulated market of significant size.

The Commission has approved proposals related to the listing and trading of funds that would primarily hold CME Bitcoin Futures that are registered under the Securities Act of 1933 (''Bitcoin Futures ETPs''),[15] finding that the CME Bitcoin Futures market represents a regulated market of significant size. Meanwhile, the Commission has continued to disapprove proposals to list and trade funds that would hold spot bitcoin on the seemingly conflicting basis that the CME Bitcoin Futures market is not a regulated market of significant size.[16] In the recently decided *Grayscale Investments, LLC* v. *Securities and Exchange Commission,*[17] however, the court resolved this conflict by finding that the SEC had failed to provide a coherent explanation as to why it had approved the Bitcoin Futures ETPs while disapproving the proposal to list and trade shares of the Grayscale Bitcoin Trust and vacating the disapproval order.[18]

As further discussed below, both the Exchange and the Sponsor believe that this proposal and the included analysis are sufficient to establish that the CME ETH Futures market represents a regulated market of significant size as it relates both to the CME ETH Futures market and to the spot ETH market and that this proposal should be approved.

Investment Objective

According to the Registration Statement, the investment objective of the Trust is for the Shares to reflect the spot price of Ether as measured by using the Lukka Prime Reference Rate less the Trust's expenses and other liabilities. In seeking to achieve its investment objective, the Trust will hold Ether (''ETH'') and will value its Shares daily based on the reported Lukka Prime Reference Rate (the ''Benchmark''), which is calculated based on prices contributed by exchanges that are determined by Lukka, Inc., (the ''Benchmark Provider'') an independent third-party digital asset company. The Trust is not actively managed.

The Benchmark

As described in the Registration Statement, the Fund will use the Benchmark to calculate the Trust's NAV. The Benchmark is designed to be a robust price for ETH in USD and there is no component other than ETH in the index. The underlying exchanges are sourced from the Benchmark Provider. As of December 2022, the following exchanges are considered to be eligible exchanges the Benchmark Provider: Binance, Bitfinex, Bitflyer, Bittrex, Bitstamp, Coinbase, Crypto.com, Gemini, HitBTC, Huobi, Kraken, KuCoin, OKEx, Poloniex (collectively, ''Benchmark Pricing Sources''). The Benchmark Provider reviews eligible exchanges quarterly. In determining which exchanges to include, the Benchmark Provider evaluates each exchange using proprietary ratings criteria. The Benchmark Provider constantly reassesses the exchanges to be eligible for inclusion in the Benchmark, and makes adjustments as needed.

In determining the value of ETH, the Benchmark Provider applies a five-step weighting process for identifying the principal exchange for Ether and the last price on that exchange. A Base Exchange Score (''BES'') that takes into account certain criteria is assigned to each eligible exchange in order to select the most appropriate primary exchange and then an executed exchange price is determined at 4:00 p.m. Eastern time.

Step 1: Assign each exchange for Ether and U.S. Dollars a BES reflecting static exchange characteristics such as oversight, microstructure and technology.

Step 2: Adjust the BES based on the relative monthly volume each exchange services. This new score is the Volume Adjusted Score (''VAS'').

Step 3: Decay the adjusted score based on the time passed since last trade on exchange, assessing the level of activity in the market by considering the frequency (volume) of trades. The decay factor reflects the time since the last trade on the exchange. This is the final Decayed Volume Adjusted Score (DVAS), which reflects freshness of data by tracking most recent trades.

Step 4: Rank the exchanges by the DVAS score and designate the highest-ranking exchange as the Principal Market for that point in time—the principal market is the exchange with highest DVAS.

Step 5: An executed exchange price is used to represent fair market value at 4:00 p.m. Eastern time.

Availability of Information

In addition to the price transparency of the Benchmark, the Trust will provide information regarding the Trust's ETH holdings as well as additional data regarding the Trust. The Trust will provide an Intraday Indicative Value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.). The IIV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during Regular Trading Hours to reflect changes in the value of the Trust's ETH holdings during the trading day.

The IIV disseminated during Regular Trading Hours should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the Exchange's Regular Trading Hours by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

The website for the Trust, which will be publicly accessible at no charge, will contain the following information: (a)

[14] *See* Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018). This proposal was subsequently disapproved by the Commission. *See* Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018) (the ''Winklevoss Order''). Prior orders from the Commission have pointed out that in every prior approval order for Commodity-Based Trust Shares, there has been a derivatives market that represents the regulated market of significant size, generally a Commodity Futures Trading Commission (the ''CFTC'') regulated futures market. Further to this point, the Commission's prior orders have noted that the spot commodities and currency markets for which it has previously approved spot ETPs are generally unregulated and that the Commission relied on the underlying futures market as the regulated market of significant size that formed the basis for approving the series of Currency and Commodity-Based Trust Shares, including gold, silver, platinum, palladium, copper, and other commodities and currencies. The Commission specifically noted in the Winklevoss Order that the approval order issued related to the first spot gold ETP ''was based on an assumption that the currency market and the spot gold market were largely unregulated.'' *See* Winklevoss Order at 37592. As such, the regulated market of significant size test does not require that the spot Ether market be regulated in order for the Commission to approve this proposal, and precedent makes clear that an underlying market for a spot commodity or currency being a regulated market would actually be an exception to the norm. These largely unregulated currency and commodity markets do not provide the same protections as the markets that are subject to the Commission's oversight, but the Commission has consistently looked to surveillance sharing agreements with the underlying futures market in order to determine whether such products were consistent with the Act.

[15] *See* Exchange Act Release No. 94620 (April 6, 2022), 87 FR 21676 (April 12, 2022) (the ''Teucrium Approval'') and 94853 (May 5, 2022) (collectively, with the Teucrium Approval, the ''Bitcoin Futures Approvals'').

[16] The proposed spot bitcoin funds are nearly identical to the Trust but proposed to hold bitcoin instead of ETH (''Spot Bitcoin ETPs'').

[17] *Grayscale Investments, LLC* v. *Securities and Exchange Commission,* et al., Case No. 22–1142 (the ''Grayscale Order'').

[18] *Id.*

the current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the BZX Official Closing Price [19] in relation to the NAV as of the time the NAV is calculated and a calculation of the premium or discount of such price against such NAV; (c) data in chart form displaying the frequency distribution of discounts and premiums of the Official Closing Price against the NAV, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The Trust will also disseminate the Trust's holdings on a daily basis on the Trust's website. The price of ETH will be made available by one or more major market data vendors, updated at least every 15 seconds during Regular Trading Hours. Information about the Benchmark, including key elements of how the Benchmark is calculated, will be publicly available at *https://www.lukka.tech/.*

The NAV for the Trust will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association (''CTA'').

Quotation and last sale information for ETH is widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters, as well as the Benchmark. Information relating to trading, including price and volume information, in ETH is available from major market data vendors and from the exchanges on which ETH are traded. Depth of book information is also available from ETH exchanges. The normal trading hours for ETH exchanges are 24 hours per day, 365 days per year.

The ETH Custodian

The Custodian's services (i) allow ETH to be deposited from a public blockchain address to the Trust's ETH account and (ii) allow ETH to be withdrawn from the ETH account to a public blockchain address as instructed by the Trust. The Custody Agreement requires the Custodian to hold the Trust's ETH in cold storage, unless required to facilitate withdrawals as a temporary measure. The Custodian will use segregated cold storage ETH addresses for the Trust which are separate from the ETH addresses that the Custodian uses for its other customers and which are directly verifiable via the ETH blockchain. The Custodian will safeguard the private keys to the ETH associated with the Trust's ETH account. The Custodian will at all times record and identify in its books and records that such ETH constitutes the property of the Trust. The Custodian will not withdraw the Trust's ETH from the Trust's account with the Custodian, or loan, hypothecate, pledge or otherwise encumber the Trust's ETH, without the Trust's instruction. If the custody agreement terminates, the Sponsor may appoint another custodian and the Trust may enter into a custodian agreement with such custodian.

Net Asset Value

NAV means the total assets of the Trust including, but not limited to, all ETH and cash, if any, less total liabilities of the Trust, each determined on the basis of generally accepted accounting principles. The Administrator will determine the NAV of the Trust on each day that the Exchange is open for regular trading, as promptly as practical after 4:00 p.m. EST. The NAV of the Trust is the aggregate value of the Trust's assets less its estimated accrued but unpaid liabilities (which include accrued expenses). In determining the Trust's NAV, the Administrator values the ETH held by the Trust based on the price set by the Benchmark as of 4:00 p.m. EST. The Administrator also determines the NAV per Share.

Creation and Redemption of Shares

According to the Registration Statement, on any business day, an authorized participant may place an order to create one or more baskets. Purchase orders must be placed by 4:00 p.m. Eastern Time, or the close of regular trading on the Exchange, whichever is earlier. The day on which an order is received is considered the purchase order date. The total deposit of ETH required is an amount of ETH that is in the same proportion to the total assets of the Trust, net of accrued expenses and other liabilities, on the date the order to purchase is properly received, as the number of Shares to be created under the purchase order is in proportion to the total number of Shares outstanding on the date the order is received. Each night, the Sponsor will publish the amount of ETH that will be required in exchange for each creation order. The Administrator determines the required deposit for a given day by dividing the number of ETH held by the Trust as of the opening of business on that business day, adjusted for the amount of ETH constituting estimated accrued but unpaid fees and expenses of the Trust as of the opening of business on that business day, by the quotient of the number of Shares outstanding at the opening of business divided by 5,000. The procedures by which an authorized participant can redeem one or more Creation Baskets mirror the procedures for the creation of Creation Baskets.

Commodity-Based Trust Shares—Rule 14.11(e)(4)

The Shares will be subject to BZX Rule 14.11(e)(4), which sets forth the initial and continued listing criteria applicable to Commodity-Based Trust Shares. The Exchange will obtain a representation that the Trust's NAV will be calculated daily and that these values and information about the assets of the Trust will be made available to all market participants at the same time. The Exchange notes that, as defined in Rule 14.11(e)(4)(C)(i), the Shares will be: (a) issued by a trust that holds a specified commodity [20] deposited with the trust; (b) issued by such trust in a specified aggregate minimum number in return for a deposit of a quantity of the underlying commodity; and (c) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such trust which will deliver to the redeeming holder the quantity of the underlying commodity.

Upon termination of the Trust, the Shares will be removed from listing. The Trustee, Delaware Trust Company, is a trust company having substantial capital and surplus and the experience and facilities for handling corporate trust business, as required under Rule 14.11(e)(4)(E)(iv)(a) and that no change will be made to the trustee without prior notice to and approval of the Exchange. The Exchange also notes that, pursuant to Rule 14.11(e)(4)(F), neither the Exchange nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions or delays in calculating or disseminating any underlying commodity value, the

[19] As defined in Rule 11.23(a)(3), the term ''BZX Official Closing Price'' shall mean the price disseminated to the consolidated tape as the market center closing trade.

[20] For purposes of Rule 14.11(e)(4), the term commodity takes on the definition of the term as provided in the Commodity Exchange Act. The CFTC has stated that: ''Certain digital assets, including BTC, ETH, LTC, and at least two fiat-backed stablecoins, tether (''USDT'') and the Binance USD (''BUSD''), as well as other virtual currencies as alleged herein, are ''commodities,'' as defined under Section 1a(9) of the [Commodities Exchange] Act, 7 U.S.C. 1a(9).'' *See* Commodity Futures Trading Commission v. Changpeng Zhao, Binance Holdings Limited, Binance Holdings (IE) Limited, Binance (Services) Holdings Limited, and Samuel Lim, March 27, 2023 at 9.

current value of the underlying commodity required to be deposited to the Trust in connection with issuance of Commodity-Based Trust Shares; resulting from any negligent act or omission by the Exchange, or any agent of the Exchange, or any act, condition or cause beyond the reasonable control of the Exchange, its agent, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission or delay in the reports of transactions in an underlying commodity. Finally, as required in Rule 14.11(e)(4)(G), the Exchange notes that any registered market maker (''Market Maker'') in the Shares must file with the Exchange in a manner prescribed by the Exchange and keep current a list identifying all accounts for trading in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, which the registered Market Maker may have or over which it may exercise investment discretion. No registered Market Maker shall trade in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, in an account in which a registered Market Maker, directly or indirectly, controls trading activities, or has a direct interest in the profits or losses thereof, which has not been reported to the Exchange as required by this Rule. In addition to the existing obligations under Exchange rules regarding the production of books and records (see, *e.g.,* Rule 4.2), the registered Market Maker in Commodity-Based Trust Shares shall make available to the Exchange such books, records or other information pertaining to transactions by such entity or registered or non-registered employee affiliated with such entity for its or their own accounts for trading the underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, as may be requested by the Exchange.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) the extent to which trading is not occurring in the ETH underlying the Shares; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(e)(4)(E)(ii), which sets forth circumstances under which trading in the Shares may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. BZX will allow trading in the Shares during all trading sessions on the Exchange. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in BZX Rule 11.11(a) the minimum price variation for quoting and entry of orders in securities traded on the Exchange is $0.01 where the price is greater than $1.00 per share or $0.0001 where the price is less than $1.00 per share.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares and ETH Futures via the Intermarket Surveillance Group (''ISG''), from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[21]

[21] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (i) the procedures for the creation and redemption of Baskets (and that the Shares are not individually redeemable); (ii) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (iii) how information regarding the IIV and the Trust's NAV are disseminated; (iv) the risks involved in trading the Shares outside of Regular Trading Hours [22] when an updated IIV will not be calculated or publicly disseminated; (v) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (vi) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Shares. Members purchasing the Shares for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

CME ETH Futures [23]

CME began offering trading in Ether Futures in February 2021. Each contract represents 50 ETH and is based on the CME CF Ether-Dollar Reference Rate.[24] The contracts trade and settle like other cash-settled commodity futures contracts. Most measurable metrics related to CME ETH Futures have generally trended up since launch, although some metrics have slowed recently. For example, there were 76,293 CME ETH Futures contracts traded in July 2023 (approximately $7.3 billion) compared to 70,305 ($11.1 billion) and 158,409 ($7.5 billion) contracts traded in July 2021, and July

[22] Regular Trading Hours is the time between 9:30 a.m. and 4:00 p.m. Eastern Time.

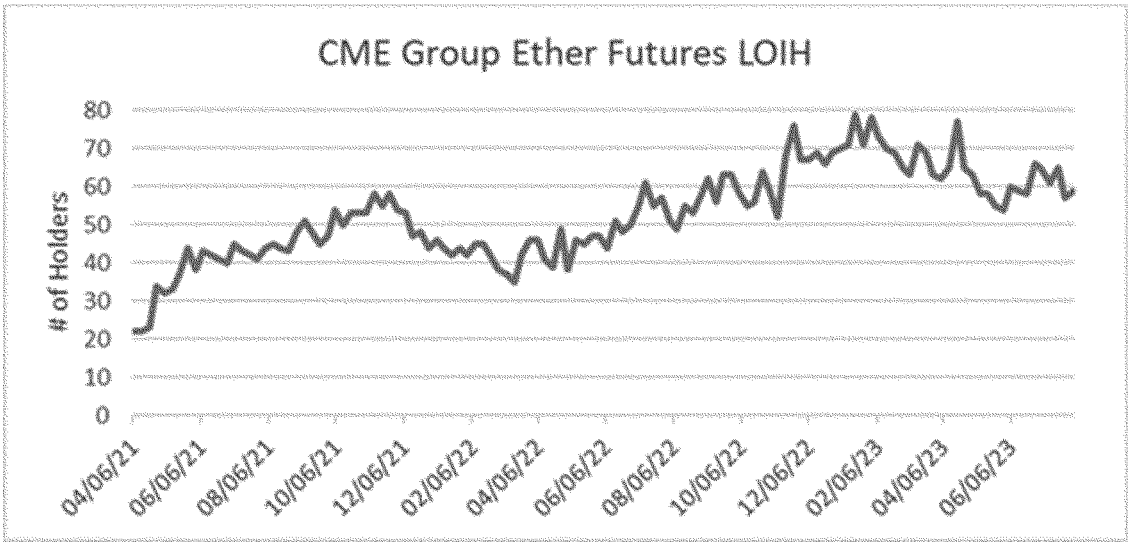
[23] Unless otherwise noted, all data and analysis presented in this section and referenced elsewhere in the filing has been provided by the Sponsor.

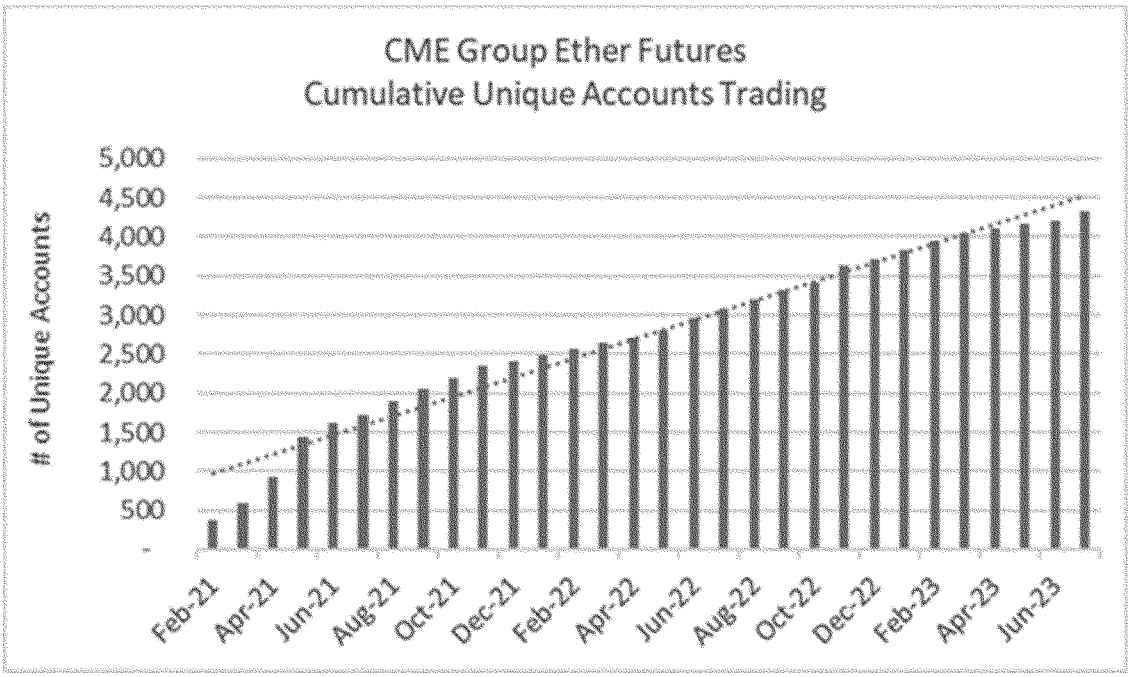
[24] The CME CF Ether-Dollar Reference Rate is based on a publicly available calculation methodology based on pricing sourced from several crypto exchanges and trading platforms, including Bitstamp, Coinbase, Gemini, itBit, Kraken, and LMAX Digital.

2022 respectively.[25] The Sponsor's research indicates daily correlation between the spot ETH and the CME ETH Futures is 0.998 from the period of 9/1/22 through 9/1/23.

The number of large open interest holders [26] and unique accounts trading CME ETH Futures have both increased, even in the face of heightened Ether price volatility.

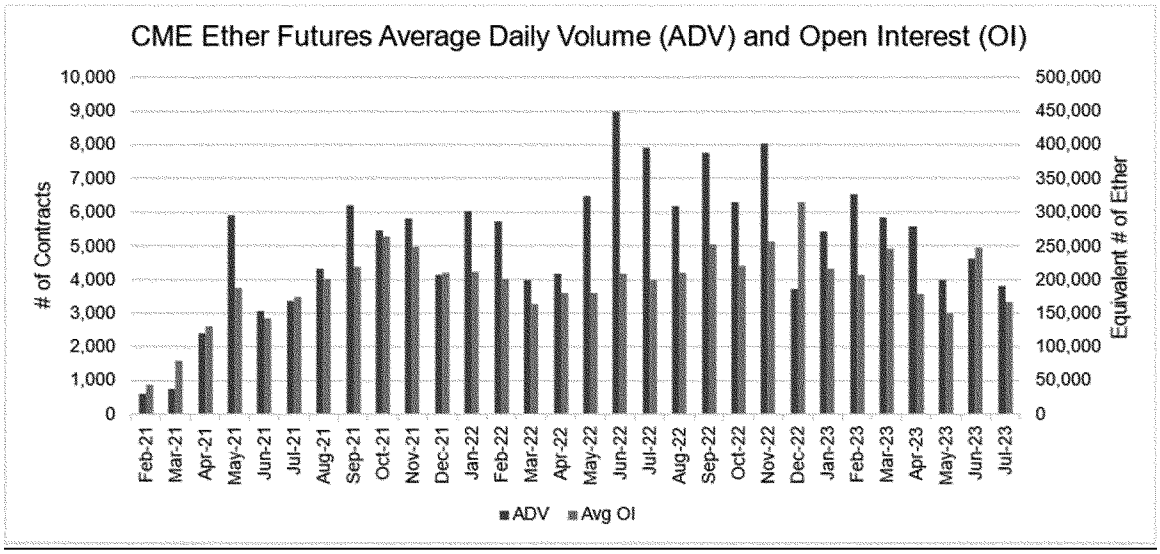
BILLING CODE 8011–01–P

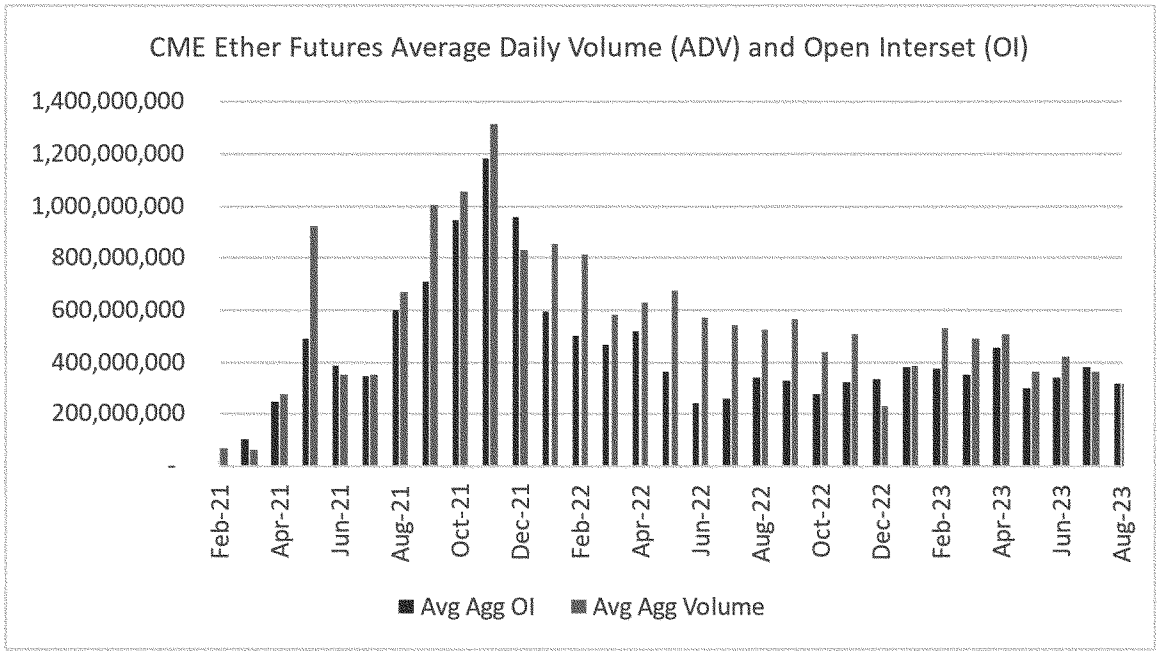




[25] Source: CME, 7/31/23.

[26] A large open interest holder in CME ETH Futures is an entity that holds at least 25 contracts, which is the equivalent of 1250 ether. At a price of approximately $1,867 per Ether on 7/31/2023, more than 59 firms had outstanding positions of greater than $2.3 million in CME ETH Futures.





BILLING CODE 8011–01–C

Section 6(b)(5) and the Applicable Standards

The Commission has approved numerous series of Trust Issued Receipts,[27] including Commodity-Based Trust Shares,[28] to be listed on U.S. national securities exchanges. In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act, specifically including: (i) the requirement that a national securities exchange's rules are designed to prevent fraudulent and manipulative acts and practices; [29] and (ii) the requirement that an exchange proposal be designed, in general, to protect investors and the public interest. The Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that this filing sufficiently

[27] *See* Exchange Rule 14.11(f).

[28] Commodity-Based Trust Shares, as described in Exchange Rule 14.11(e)(4), are a type of Trust Issued Receipt.

[29] The Exchange believes that ETH is resistant to price manipulation and that ''other means to prevent fraudulent and manipulative acts and practices'' exist to justify dispensing with the requisite surveillance sharing agreement. The geographically diverse and continuous nature of ETH trading render it difficult and prohibitively costly to manipulate the price of ETH. The fragmentation across ETH platforms, the relatively slow speed of transactions, and the capital necessary to maintain a significant presence on each trading platform make manipulation of ETH prices through continuous trading activity challenging. To the extent that there are ETH exchanges engaged in or allowing wash trading or other activity intended to manipulate the price of ETH on other markets, such pricing does not normally impact prices on other exchange because participants will generally ignore markets with quotes that they deem non-executable. Moreover, the linkage between the ETH markets and the presence of arbitrageurs in those markets means that the manipulation of the price of ETH price on any single venue would require manipulation of the global ETH price in order to be effective. Arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular ETH exchange or OTC platform. As a result, the potential for manipulation on a trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences.

demonstrates that the CME ETH Futures market represents a regulated market of significant size and that, on the whole, the manipulation concerns previously articulated by the Commission are sufficiently mitigated to the point that they are outweighed by quantifiable investor protection issues that would be resolved by approving this proposal.

(i) Designed To Prevent Fraudulent and Manipulative Acts and Practices

In order to meet this standard in a proposal to list and trade a series of Commodity-Based Trust Shares, the Commission requires that an exchange demonstrate that there is a comprehensive surveillance-sharing agreement in place [30] with a regulated market of significant size. Both the Exchange and CME are members of ISG. The only remaining issue to be addressed is whether the ETH Futures market constitutes a market of significant size, which both the Exchange and the Sponsor believe that it does. The terms ''significant market'' and ''market of significant size'' include a market (or group of markets) as to which: (a) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to manipulate the ETP, so that a surveillance-sharing agreement would assist the listing exchange in detecting and deterring misconduct; and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[31]

The Commission has also recognized that the ''regulated market of significant size'' standard is not the only means for satisfying Section 6(b)(5) of the act, specifically providing that a listing exchange could demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement.[32] [33]

(a) Manipulation of the ETP

The significant market test requires that there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to manipulate the ETP, so that a surveillance-sharing agreement would assist the listing exchange in detecting and deterring misconduct.

In light of the similarly high correlation between spot ETH/CME ETH Futures and spot bitcoin/CME Bitcoin Futures (.998 vs. .999, respectively), applying the same rationale that the Commission applied to a Bitcoin Futures ETF in the Bitcoin Futures Approvals also indicates that this test is satisfied for this proposal. In the Teucrium Approval, the SEC stated:

> The CME ''comprehensively surveils futures market conditions and price movements on a real-time and ongoing basis in order to detect and prevent price distortions, including price distortions caused by manipulative efforts.'' Thus, the CME's surveillance can reasonably be relied upon to capture the effects on the CME futures market caused by a person attempting to manipulate the proposed futures ETP by manipulating the price of CME futures contracts, whether that attempt is made by directly trading on the CME futures market or indirectly by trading outside of the CME futures market. As such, when the CME shares its surveillance information with Arca, the information would assist in detecting and deterring fraudulent or manipulative misconduct related to the non-cash assets held by the proposed ETP.[34]

The assumptions from this statement are also true for CME ETH Futures. CME ETH Futures pricing is based on pricing from spot ETH markets. The statement from the Teucrium Approval that ''CME's surveillance can reasonably be relied upon to capture the effects on the CME BTC futures market caused by a person attempting to manipulate the proposed futures ETP by manipulating the price of CME BTC futures contracts . . . indirectly by trading outside of the CME BTC futures market,'' makes clear that the Commission believes that CME's surveillance can capture the effects of trading on the relevant spot markets on the pricing of CME BTC Futures. This same logic would extend to CME ETH Futures markets where CME's surveillance would be able to capture the effects of trading on the relevant spot markets on the pricing of CME ETH Futures. This was further acknowledged in the Grayscale lawsuit when Judge Rao stated ''. . . the Commission in the Teucrium order recognizes that the futures prices are influenced by the spot prices, and the Commission concludes in approving futures ETPs that any fraud on the spot market can be adequately addressed by the fact that the futures market is a regulated one . . .'' The Exchange agrees with the Commission on this point and notes that the pricing mechanism applicable to the Shares is similar to that of the CME ETH Futures. This view is also consistent with the Sponsor's research.

As such, the part (a) of the significant market test outlined above is satisfied and that common membership in ISG between the Exchange and CME would assist the listing exchange in detecting and deterring misconduct in the Shares in the same way that it would be for both Bitcoin Futures ETPs and Spot Bitcoin ETPs.

(b) Predominant Influence on Prices in Spot and ETH Futures

The Exchange and Sponsor also believe that trading in the Shares would not be the predominant force on prices in the CME ETH Futures market for a number of reasons. First, because the Trust would not hold CME ETH Futures contracts, the only way that it could be the predominant force on prices in that market is through the spot markets that CME ETH Futures contracts use for pricing.[35] The Sponsor notes that ETH total 24-hour spot trading volume has

[30] As previously articulated by the Commission, ''The standard requires such surveillance-sharing agreements since ''they provide a necessary deterrent to manipulation because they facilitate the availability of information needed to fully investigate a manipulation if it were to occur.'' The Commission has emphasized that it is essential for an exchange listing a derivative securities product to enter into a surveillance-sharing agreement with markets trading underlying securities for the listing exchange to have the ability to obtain information necessary to detect, investigate, and deter fraud and market manipulation, as well as violations of exchange rules and applicable federal securities laws and rules. The hallmarks of a surveillance-sharing agreement are that the agreement provides for the sharing of information about market trading activity, clearing activity, and customer identity; that the parties to the agreement have reasonable ability to obtain access to and produce requested information; and that no existing rules, laws, or practices would impede one party to the agreement from obtaining this information from, or producing it to, the other party.'' The Commission has historically held that joint membership in the ISG constitutes such a surveillances sharing agreement. *See* Securities Exchange Act Release No. 88284 (February 26, 2020), 85 FR 12595 (March 3, 2020) (SR–NYSEArca–2019–39) (the ''Wilshire Phoenix Disapproval'').

[31] *See* Wilshire Phoenix Disapproval.

[32] *See* Winklevoss Order at 37580. The Commission has also specifically noted that it ''is not applying a 'cannot be manipulated' standard; instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met.'' *Id.* at 37582.

[33] According to reports, the Commission is poised to allow the launch of ETFs registered under the Investment Company Act of 1940, as amended (the ''1940 Act''), that provide exposure to ETH primarily through CME ETH Futures (''ETH Futures ETFs'') as early as October 2023. Allowing such products to list and trade is a productive first step in providing U.S. investors and traders with transparent, exchange-listed tools for expressing a view on ETH. *https://www.bloomberg.com/news/articles/2023-08-17/sec-said-to-be-poised-to-allow-us-debut-of-ether-futures-etfs-eth#xj4y7vzkg.*

[34] *See* Teucrium Approal at 21679.

[35] This logic is reflected by the court in the Grayscale Order at 17–18. Specifically, the court found that ''Because Grayscale owns no futures contracts, trading in Grayscale can affect the futures market only through the spot market . . . But Grayscale holds just 3.4 percent of outstanding bitcoin, and the Commission did not suggest Grayscale can dominate the price of bitcoin.''

averaged $9.4B over the year ending September 1, 2023,[36] with approximately $950M occurring on venues whose trades are included in the sponsor's benchmark.[37] The Sponsor expects that the Trust would represent a very small percentage of this daily trading volume in the spot ETH market even in its most aggressive projections for the Trust's assets and, thus, the Trust would not have an impact on the spot market and therefore could not be the predominant force on prices in the CME ETH Futures market. Second, much like the CME Bitcoin Futures market, the CME ETH Futures market has progressed and matured significantly. As the court found in the Grayscale Order ''Because the spot market is deeper and more liquid than the futures market, manipulation should be more difficult, not less.'' The Exchange and sponsor agree with this sentiment and believe it applies equally to the spot ETH and CME ETH Futures markets.

(c) Other Means To Prevent Fraudulent and Manipulative Acts and Practices

As noted above, the Commission also permits a listing exchange to demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement. The Exchange and Sponsor believe that such conditions are present.

The Exchange is proposing to take additional steps to those described above to supplement its ability to obtain information that would be helpful in detecting, investigating, and deterring fraud and market manipulation in the Commodity-Based Trust Shares. On June 21, 2023, the Exchange reached an agreement on terms with Coinbase, Inc. (''Coinbase''), an operator of a United States-based spot trading platform for ETH that represents a substantial portion of US-based and USD denominated ETH trading,[38] to enter into a surveillance-sharing agreement (''Spot Crypto SSA'') and executed an associated term sheet. Based on this agreement on terms, the Exchange and Coinbase will finalize and execute a definitive agreement that the parties expect to be executed prior to allowing trading of the Commodity-Based Trust Shares.

The Spot Crypto SSA is expected to be a bilateral surveillance-sharing agreement between the Exchange and Coinbase that is intended to supplement the Exchange's market surveillance program. The Spot Crypto SSA is expected to have the hallmarks of a surveillance-sharing agreement between two members of the ISG, which would give the Exchange supplemental access to data regarding spot ETH trades on Coinbase where the Exchange determines it is necessary as part of its surveillance program for the Commodity-Based Trust Shares.[39] This means that the Exchange expects to receive market data for orders and trades from Coinbase, which it will utilize in surveillance of the trading of Commodity-Based Trust Shares. In addition, the Exchange can request further information from Coinbase related to spot ETH trading activity on the Coinbase exchange platform, if the Exchange determines that such information would be necessary to detect and investigate potential manipulation in the trading of the Commodity-Based Trust Shares.[40]

(ii) Designed To Protect Investors and the Public Interest

The Exchange believes that the proposal is designed to protect investors and the public interest. Over the past several years, U.S. investor exposure to ETH through OTC ETH Funds is greater than $5 billion. With that growth, so too has grown the quantifiable investor protection issues to U.S. investors through premium/discount volatility and management fees for OTC ETH Funds. The Exchange believes that, as described above, the concerns related to the prevention of fraudulent and manipulative acts and practices have been sufficiently addressed to be consistent with the Act and, to the extent that the Commission disagrees with that assertion, such concerns are now at the very least outweighed by investor protection concerns. As such, the Exchange believes that approving this proposal (and comparable proposals) provides the Commission with the opportunity to allow U.S. investors with access to ETH in a regulated and transparent exchange-traded vehicle that would act to limit risk to U.S. investors by: (i) reducing premium and discount volatility; (ii) reducing management fees through meaningful competition; (iii) reducing risks and costs associated with investing in ETH Futures ETFs and operating companies that are imperfect proxies for ETH exposure; and (iv) providing an alternative to custodying spot ETH.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[41] in general and Section 6(b)(5) of the Act[42] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission has approved numerous series of Trust Issued Receipts, including Commodity-Based Trust Shares, to be listed on U.S. national securities exchanges. In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act, specifically including: (i) the requirement that a national securities exchange's rules are designed to prevent fraudulent and manipulative acts and practices;[43] and (ii) the requirement that an exchange proposal be designed, in general, to

[36] Source: TokenTerminal.

[37] Source: VanEck research, CryptoCompare.

[38] According to a report from The Block, Coinbase represented 45%% of USD denominated exchange trading volume in August 2023. *https://www.theblock.co/data/crypto-markets/spot/usd-support-exchange-volume-market-share.*

[39] For additional information regarding ISG and the hallmarks of surveillance-sharing between ISG members, see *https://isgportal.org/overview.*

[40] The Exchange also notes that it already has in place ISG-like surveillance sharing agreement with Cboe Digital Exchange, LLC and Cboe Clear Digital, LLC.

[41] 15 U.S.C. 78f.

[42] 15 U.S.C. 78f(b)(5).

[43] The Exchange believes that ETH is resistant to price manipulation and that ''other means to prevent fraudulent and manipulative acts and practices'' exist to justify dispensing with the requisite surveillance sharing agreement. The geographically diverse and continuous nature of ETH trading render it difficult and prohibitively costly to manipulate the price of ETH. The fragmentation across ETH platforms, the relatively slow speed of transactions, and the capital necessary to maintain a significant presence on each trading platform make manipulation of ETH prices through continuous trading activity challenging. To the extent that there are ETH exchanges engaged in or allowing wash trading or other activity intended to manipulate the price of ETH on other markets, such pricing does not normally impact prices on other exchange because participants will generally ignore markets with quotes that they deem non-executable. Moreover, the linkage between the ETH markets and the presence of arbitrageurs in those markets means that the manipulation of the price of ETH price on any single venue would require manipulation of the global ETH price in order to be effective. Arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular ETH exchange or OTC platform. As a result, the potential for manipulation on a trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences.

protect investors and the public interest. The Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that this filing sufficiently demonstrates that the CME ETH Futures market represents a regulated market of significant size and that, on the whole, the manipulation concerns previously articulated by the Commission are sufficiently mitigated to the point that they are outweighed by quantifiable investor protection issues that would be resolved by approving this proposal.

(i) Designed To Prevent Fraudulent and Manipulative Acts and Practices

In order to meet this standard in a proposal to list and trade a series of Commodity-Based Trust Shares, the Commission requires that an exchange demonstrate that there is a comprehensive surveillance-sharing agreement in place with a regulated market of significant size. Both the Exchange and CME are members of ISG. The only remaining issue to be addressed is whether the ETH Futures market constitutes a market of significant size, which both the Exchange and the Sponsor believe that it does. The terms ''significant market'' and ''market of significant size'' include a market (or group of markets) as to which: (a) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to manipulate the ETP, so that a surveillance-sharing agreement would assist the listing exchange in detecting and deterring misconduct; and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[44]

The Commission has also recognized that the ''regulated market of significant size'' standard is not the only means for satisfying Section 6(b)(5) of the act, specifically providing that a listing exchange could demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement.[45] [46]

(a) Manipulation of the ETP

The significant market test requires that there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to manipulate the ETP, so that a surveillance-sharing agreement would assist the listing exchange in detecting and deterring misconduct.

In light of the similarly high correlation between spot ETH/CME ETH Futures and spot bitcoin/CME Bitcoin Futures (.998 vs. .999, respectively), applying the same rationale that the Commission applied to a Bitcoin Futures ETF in the Bitcoin Futures Approvals also indicates that this test is satisfied for this proposal. In the Teucrium Approval, the SEC stated:

> The CME ''comprehensively surveils futures market conditions and price movements on a real-time and ongoing basis in order to detect and prevent price distortions, including price distortions caused by manipulative efforts.'' Thus, the CME's surveillance can reasonably be relied upon to capture the effects on the CME futures market caused by a person attempting to manipulate the proposed futures ETP by manipulating the price of CME futures contracts, whether that attempt is made by directly trading on the CME futures market or indirectly by trading outside of the CME futures market. As such, when the CME shares its surveillance information with Arca, the information would assist in detecting and deterring fraudulent or manipulative misconduct related to the non-cash assets held by the proposed ETP.[47]

The assumptions from this statement are also true for CME ETH Futures. CME ETH Futures pricing is based on pricing from spot ETH markets. The statement from the Teucrium Approval that ''CME's surveillance can reasonably be relied upon to capture the effects on the CME BTC futures market caused by a person attempting to manipulate the proposed futures ETP by manipulating the price of CME BTC futures contracts . . . indirectly by trading outside of the CME BTC futures market,'' makes clear that the Commission believes that CME's surveillance can capture the effects of trading on the relevant spot markets on the pricing of CME BTC Futures. This same logic would extend to CME ETH Futures markets where CME's surveillance would be able to capture the effects of trading on the relevant spot markets on the pricing of CME ETH Futures. This was further acknowledged in the Grayscale lawsuit when Judge Rao stated ''. . . the Commission in the Teucrium order recognizes that the futures prices are influenced by the spot prices, and the Commission concludes in approving futures ETPs that any fraud on the spot market can be adequately addressed by the fact that the futures market is a regulated one . . .'' The Exchange agrees with the Commission on this point and notes that the pricing mechanism applicable to the Shares is similar to that of the CME ETH Futures. This view is also consistent with the Sponsor's research.

As such, the part (a) of the significant market test outlined above is satisfied and that common membership in ISG between the Exchange and CME would assist the listing exchange in detecting and deterring misconduct in the Shares in the same way that it would be for both Bitcoin Futures ETPs and Spot Bitcoin ETPs.

(b) Predominant Influence on Prices in Spot and ETH Futures

The Exchange and Sponsor also believe that trading in the Shares would not be the predominant force on prices in the CME ETH Futures market for a number of reasons. First, because the Trust would not hold CME ETH Futures contracts, the only way that it could be the predominant force on prices in that market is through the spot markets that CME ETH Futures contracts use for pricing.[48] The Sponsor notes that ETH total 24-hour spot trading volume has averaged $9.4B over the year ending September 1, 2023,[49] with approximately $950M occurring on venues whose trades are included in the sponsor's benchmark.[50] The Sponsor expects that the Trust would represent a very small percentage of this daily trading volume in the spot ETH market even in its most aggressive projections for the Trust's assets and, thus, the Trust would not have an impact on the spot market and therefore could not be the predominant force on prices in the CME ETH Futures market. Second, much like the CME Bitcoin Futures market, the CME ETH Futures market has progressed and matured significantly.

[44] *See* Wilshire Phoenix Disapproval.

[45] *See* Winklevoss Order at 37580. The Commission has also specifically noted that it ''is not applying a 'cannot be manipulated' standard; instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met.'' *Id.* at 37582.

[46] According to reports, the Commission is poised to allow the launch of ETFs registered under the Investment Company Act of 1940, as amended (the ''1940 Act''), that provide exposure to ETH primarily through CME ETH Futures (''ETH Futures ETFs'') as early as October 2023. Allowing such products to list and trade is a productive first step in providing U.S. investors and traders with transparent, exchange-listed tools for expressing a view on ETH. *https://www.bloomberg.com/news/articles/2023-08-17/sec-said-to-be-poised-to-allow-us-debut-of-ether-futures-etfs-eth#xj4y7vzkg.*

[47] *See* Teucrium Approval at 21679.

[48] This logic is reflected by the court in the Grayscale Order at 17–18. Specifically, the court found that ''Because Grayscale owns no futures contracts, trading in Grayscale can affect the futures market only through the spot market . . . But Grayscale holds just 3.4 percent of outstanding bitcoin, and the Commission did not suggest Grayscale can dominate the price of bitcoin.''

[49] Source: TokenTerminal.

[50] Source: VanEck research, CryptoCompare.

As the court found in the Grayscale Order, ''Because the spot market is deeper and more liquid than the futures market, manipulation should be more difficult, not less.'' The Exchange and Sponsor agree with this sentiment and believe it applies equally to the spot ETH and CME ETH Futures markets.

(c) Other Means To Prevent Fraudulent and Manipulative Acts and Practices

As noted above, the Commission also permits a listing exchange to demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement. The Exchange and Sponsor believe that such conditions are present.

The Exchange is proposing to take additional steps to those described above to supplement its ability to obtain information that would be helpful in detecting, investigating, and deterring fraud and market manipulation in the Commodity-Based Trust Shares. On June 21, 2023, the Exchange reached an agreement on terms with Coinbase, Inc. (''Coinbase''), an operator of a United States-based spot trading platform for ETH that represents a substantial portion of US-based and USD denominated ETH trading, to enter into a Spot Crypto SSA and executed an associated term sheet. Based on this agreement on terms, the Exchange and Coinbase will finalize and execute a definitive agreement that the parties expect to be executed prior to allowing trading of the Commodity-Based Trust Shares.

The Spot Crypto SSA is expected to be a bilateral surveillance-sharing agreement between the Exchange and Coinbase that is intended to supplement the Exchange's market surveillance program. The Spot Crypto SSA is expected to have the hallmarks of a surveillance-sharing agreement between two members of the ISG, which would give the Exchange supplemental access to data regarding spot ETH trades on Coinbase where the Exchange determines it is necessary as part of its surveillance program for the Commodity-Based Trust Shares. This means that the Exchange expects to receive market data for orders and trades from Coinbase, which it will utilize in surveillance of the trading of Commodity-Based Trust Shares. In addition, the Exchange can request further information from Coinbase related to spot ETH trading activity on the Coinbase exchange platform, if the Exchange determines that such information would be necessary to detect and investigate potential manipulation in the trading of the Commodity-Based Trust Shares.

(ii) Designed To Protect Investors and the Public Interest

The Exchange believes that the proposal is designed to protect investors and the public interest. Over the past several years, U.S. investor exposure to ETH through OTC ETH Funds is greater than $5 billion. With that growth, so too has grown the quantifiable investor protection issues to U.S. investors through premium/discount volatility and management fees for OTC ETH Funds. The Exchange believes that, as described above, the concerns related to the prevention of fraudulent and manipulative acts and practices have been sufficiently addressed to be consistent with the Act and, to the extent that the Commission disagrees with that assertion, such concerns are now at the very least outweighed by investor protection concerns. As such, the Exchange believes that approving this proposal (and comparable proposals) provides the Commission with the opportunity to allow U.S. investors with access to ETH in a regulated and transparent exchange-traded vehicle that would act to limit risk to U.S. investors by: (i) reducing premium and discount volatility; (ii) reducing management fees through meaningful competition; (iii) reducing risks and costs associated with investing in ETH Futures ETFs and operating companies that are imperfect proxies for ETH exposure; and (iv) providing an alternative to custodying spot ETH.

Commodity-Based Trust Shares—Rule 14.11(e)(4)

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed on the Exchange pursuant to the initial and continued listing criteria in Exchange Rule 14.11(e)(4). The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares and listed ETH derivatives via the ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.

Availability of Information

The Exchange also believes that the proposal promotes market transparency in that a large amount of information is currently available about ETH and will be available regarding the Trust and the Shares. In addition to the price transparency of the Index, the Trust will provide information regarding the Trust's ETH holdings as well as additional data regarding the Trust. The Trust will provide an IIV per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.). The IIV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during Regular Trading Hours to reflect changes in the value of the Trust's ETH holdings during the trading day.

The IIV disseminated during Regular Trading Hours should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the Exchange's Regular Trading Hours by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

The website for the Trust, which will be publicly accessible at no charge, will contain the following information: (a) the current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the BZX Official Closing Price in relation to the NAV as of the time the NAV is calculated and a calculation of the premium or discount of such price against such NAV; (c) data in chart form displaying the frequency distribution of discounts and premiums of the Official Closing Price against the NAV, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The Trust will also disseminate the Trust's holdings on

a daily basis on the Trust's website. The price of ETH will be made available by one or more major market data vendors, updated at least every 15 seconds during Regular Trading Hours. Information about the Index, including key elements of how the Index is calculated, will be publicly available at

The NAV for the Trust will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA.

Quotation and last sale information for ETH is widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters, as well as the Index. Information relating to trading, including price and volume information, in ETH is available from major market data vendors and from the exchanges on which ETH are traded. Depth of book information is also available from ETH exchanges. The normal trading hours for ETH exchanges are 24 hours per day, 365 days per year.

In sum, the Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act, that this filing sufficiently demonstrates that the CME ETH Futures market represents a regulated market of significant size, and that on the whole the manipulation concerns previously articulated by the Commission are sufficiently mitigated to the point that they are outweighed by investor protection issues that would be resolved by approving this proposal. For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the listing and trading of an additional exchange-traded product that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be 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–CboeBZX–2023–087 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–CboeBZX–2023–087. 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–CboeBZX–2023–087 and should be submitted on or before November 29, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[51]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–24623 Filed 11–7–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35045; File No. 812–15439]

Nomura Alternative Income Fund, et al.

November 3, 2023.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to permit certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

Applicants: Nomura Alternative Income Fund, Nomura Private Capital LLC, and NCOF, LLC.

Filing Dates: The application was filed on February 16, 2023, and amended on June 26, 2023, and September 28, 2023.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below,

[51] 17 CFR 200.30–3(a)(12).

or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on November 27, 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 emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Joshua B. Deringer, Esq., Faegre Drinker Biddle & Reath LLP, at *joshua.deringer@faegredrinker.com;* with a copy to Robert Stark, Nomura Private Capital LLC, Worldwide Plaza, 309 W 49th Street, New York, NY 10019.

FOR FURTHER INFORMATION CONTACT: Kieran G. Brown, Senior Counsel, or Terri Jordan, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' second amended and restated application, dated September 28, 2023, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system.

The SEC's EDGAR system may be searched at, *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–24663 Filed 11–7–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98848]

Order Granting Conditional Exemptive Relief, Pursuant to Section 36(a)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') and Rule 608(e) of Regulation NMS Under the Exchange Act, From Certain Requirements of the National Market System Plan Governing the Consolidated Audit Trail

November 2, 2023.

I. Introduction

In July 2012, the Securities and Exchange Commission (the ''Commission'' or the ''SEC'') adopted Rule 613 of Regulation NMS, which required national securities exchanges and national securities associations (the ''Participants'') [1] to jointly develop and submit to the Commission a national market system plan to create, implement, and maintain a consolidated audit trail (the ''CAT'').[2] The goal of Rule 613 was to create a modernized audit trail system that would provide regulators with timely access to a comprehensive set of trading data, thus enabling regulators to more efficiently and effectively analyze and reconstruct market events, monitor market behavior, conduct market analysis to support regulatory decisions, and perform surveillance, investigation, and enforcement activities. On November 15, 2016, the Commission approved the national market system plan required by Rule 613 (the ''CAT NMS Plan'').[3]

On December 16, 2020, the Commission issued two exemptive orders regarding the implementation of the CAT NMS Plan (collectively, the ''2020 Orders''). The first order, in response to a request from the Participants, granted temporary conditional relief from certain performance requirements related to the online targeted query tool (''OTQT'').[4] The second order granted temporary conditional relief from the following requirements: (1) requirements for lifecycle linkages timeframes; (2) requirements for re-processing of corrected data received after T+5; (3) linkage requirements for Securities Information Processor data (''SIP Data''); (4) reporting requirements for port-level settings; (5) requirements for lifecycle linkages between customer orders and ''representative'' orders; and (6) requirements for Participant reporting of rejected orders.[5]

On February 14, 2021, several of the Participants filed motions requesting that the Commission stay the 2020 Orders, based on their concern that portions of the orders ''interpret and apply the Plan in ways that will produce unintended adverse consequences, present implementation challenges, or both.'' [6] That same day, several of those same Participants filed corresponding petitions for judicial review with the U.S. Court of Appeals for the District of Columbia Circuit (the ''D.C. Circuit'') seeking review of the 2020 Orders.[7]

On July 8, 2022, the Commission issued a new order granting temporary exemptive relief (the ''2022 Order'').[8] The 2022 Order, which superseded the

[1] The Participants include BOX Exchange LLC, Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe C2 Exchange, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Cboe Exchange, Inc., Financial Industry Regulatory Authority, Inc., Investors' Exchange LLC, Long-Term Stock Exchange, Inc., MEMX LLC, Miami International Securities Exchange LLC, MIAX Emerald, LLC, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq GEMX, LLC, Nasdaq ISE, LLC, Nasdaq MRX, LLC, Nasdaq PHLX LLC, The Nasdaq Stock Market LLC, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc.

[2] *See* Securities Exchange Act Release No. 67457 (July 18, 2012), 77 FR 45722 (Aug. 1, 2012) (''Rule 613 Adopting Release'').

[3] Securities Exchange Act Release No. 78318 (Nov. 15, 2016), 81 FR 84696, (Nov. 23, 2016) (''CAT NMS Plan Approval Order''). The CAT NMS Plan is Exhibit A to the CAT NMS Plan Approval Order. *See* CAT NMS Plan Approval Order, at 84943–85034. The CAT NMS Plan functions as the limited liability company agreement of the jointly owned limited liability company formed under Delaware state law through which the Participants conduct the activities of the CAT (the ''Company''). Each Participant is a member of the Company and jointly owns the Company on an equal basis. The Participants submitted to the Commission a proposed amendment to the CAT NMS Plan on Aug. 29, 2019, which they designated as effective on filing. Under the amendment, the limited liability company agreement of a new limited liability company named Consolidated Audit Trail, LLC serves as the CAT NMS Plan, replacing in its entirety the CAT NMS Plan. *See* Securities Exchange Act Release No. 87149 (Sept. 27, 2019), 84 FR 52905 (Oct. 3, 2019).

[4] *See* Securities Exchange Act Release No. 90689 (Dec. 16, 2020), 85 FR 83667 (Dec. 22, 2020); *see also* Letter from Michael Simon, CAT NMS Plan Operating Committee Chair, to Vanessa Countryman, Secretary, Commission, dated Dec. 1, 2020, *available at https://catnmsplan.com/sites/default/files/2020-12/12.01.20-CAT-Exemption-Request-OTQT.pdf.*

[5] *See* Securities Exchange Act Release No. 90688 (Dec. 16, 2020), 85 FR 83634 (Dec. 22, 2020).

[6] *See* Motion for Partial Stay of Order 34–90689, at 2; Motion for Partial Stay of Order 34–90688, at 2. Financial Industry Regulatory Authority, Inc. and Long-Term Stock Exchange, Inc. did not join these motions.

[7] *See* Petition for Review, USCA Case No. 21–1065; Petition for Review, USCA Case No. 21–1066. Financial Industry Regulatory Authority, Inc., Investors Exchange LLC, Long-Term Stock Exchange, Inc., MEMX LLC, Miami International Securities Exchange LLC, MIAX Emerald, LLC, and MIAX PEARL, LLC did not join these petitions.

[8] *See* Securities Exchange Act Release No. 95234 (July 8, 2022), 87 FR 42247 (July 14, 2022).

2020 Orders, modified and/or clarified certain aspects of the 2020 Orders and gave the Participants until July 31, 2024 to either implement the functionality the Commission required for compliance with the relevant provisions of the CAT NMS Plan or to obtain Commission approval of alternative solutions that achieve the relevant regulatory objectives of Rule 613 and the CAT NMS Plan in a more cost-effective manner, including CAT NMS Plan amendments or exemptive relief. In addition, the Commission issued an order denying the Participants' stay motions, concluding that the administrative petitions to stay the 2020 Orders were ''moot'' because those orders were ''no longer in force.'' [9] On August 3, 2022, the Commission and the Participants submitted a stipulation of voluntary dismissal to the D.C. Circuit, and, on August 5, 2022, the D.C. Circuit issued an order formally dismissing the lawsuits.[10]

On September 6, 2022, in order to reserve their rights, a subset of the Participants filed a petition for review with the D.C. Circuit seeking review of the 2022 Order.[11] The Commission understood that the Participants' concerns remained generally the same as expressed with respect to the 2020 Orders. The Commission subsequently issued an order, on May 18, 2023, extending the exemptive relief provided by the 2022 Order (the ''2023 Order'') from July 31, 2024 to January 31, 2025, subject to the same conditions set forth in the 2022 Order.[12] Since 2021, the Participants and Commission staff engaged in discussions with the goal of resolving their differences with respect to the issues raised by the 2020 Orders, the 2022 Order, and the 2023 Order (the ''prior Orders'').

In light of further developments throughout this period and in connection with the parties' settlement of the pending litigation, the Commission has determined to issue a new order granting the Participants conditional exemptive relief from certain requirements of the CAT NMS Plan, which are described in more detail below.[13] If and when it takes effect, the relief granted in this Order will supersede the relief granted in the 2022 Order and the 2023 Order. This relief is to take effect upon issuance of an order by the D.C. Circuit dismissing with prejudice the Participants' petition for review of the 2022 Order. Unless and until that occurs, the 2022 Order and the 2023 Order shall continue to govern. Should the Participants file a petition for review of this Order, the relief granted herein will be rescinded by its own terms and the 2022 Order and the 2023 Order will resume governing.

II. Discussion and Exemptive Relief

Section 36(a)(1) of the Exchange Act grants the Commission the authority to ''conditionally or unconditionally exempt any person, security, or transaction . . . from any provision or provisions of [the Exchange Act] or of any rule or regulation thereunder, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.'' [14] Rule 608(e) of Regulation NMS similarly grants the Commission the authority to ''exempt from [Rule 608], either unconditionally or on specified terms and conditions, any self-regulatory organization, member thereof, or specified security, if the Commission determines that such exemption is consistent with the public interest, the protection of investors, the maintenance of fair and orderly markets and the removal of impediments to, and perfection of the mechanisms of, a national market system.'' [15]

The Commission recognizes that the Participants have expended, and continue to expend, substantial resources and effort towards the development and implementation of the CAT. However, in the 2022 Order, the Commission stated that the current functionality of the CAT does not yet comply with CAT NMS Plan requirements for the above-described areas.[16] The Participants have disagreed, and have further stated that, in many of these areas, strict compliance with the relevant CAT NMS Plan provisions would not be practical from a cost-benefit perspective.[17] In light of that disagreement, the Commission stressed in the 2022 Order its willingness to consider alternative solutions that achieve the regulatory goals of Rule 613 and the CAT NMS Plan in a more cost-effective manner.[18]

The Commission has determined that the exemptive relief granted herein—which is the product of multiple years of settlement discussions—is appropriate in the public interest and consistent with the protection of investors under section 36(a)(1) of the Exchange Act, as well as consistent with the public interest, the protection of investors, the maintenance of fair and orderly markets, and the perfection of the mechanisms of a national market system under Rule 608(e) of Regulation NMS. The Commission approved the CAT NMS Plan to help to protect investors and maintain fair and orderly markets by providing a sophisticated audit trail that improves regulators' ability to investigate potential misconduct, to reconstruct and to analyze market events, and to support regulatory decisions with detailed and accurate data, among other benefits. The conditional exemptive relief in this Order allows for the implementation of alternative regulatory solutions that continue to advance the regulatory goals that Rule 613 and the CAT NMS Plan were intended to promote, while reducing the implementation and operational costs, burdens, and/or

[9] *See* Securities Exchange Act Release No. 95235 (July 8, 2022), 87 FR 42242 (July 14, 2022).

[10] *See* Order of Dismissal, USCA Case No. 21–1065 (consolidated with USCA Case No. 21–1066).

[11] *See* Petition for Review, USCA Case No. 22–1234. Financial Industry Regulatory Authority, Inc. and Investors' Exchange LLC did not join this petition.

[12] *See* Securities Exchange Act Release No. 97530 (May 18, 2023), 88 FR 33655 (May 24, 2023).

[13] In May 2020, the Commission adopted amendments to the CAT NMS Plan that establish four Financial Accountability Milestones and set target deadlines by which these milestones must be achieved. These amendments also reduce the amount of any fees, costs, and expenses that the Participants may recover from Industry Members if the Participants fail to meet the target deadlines. *See* Securities Exchange Act Release No. 88890 (May 15, 2020), 85 FR 31322 (May 22, 2020). The Commission has stated that, to the extent that the Participants are availing themselves of exemptive relief from a CAT NMS Plan requirement, such requirement shall not be included in the requirements for a Financial Accountability Milestone, provided that the conditions of the exemption are satisfied. *See, e.g.,* Securities Exchange Act Release No. 89051 (June 11, 2020), 85 FR 36631 (June 17, 2020). In connection with issuing this Order, the Commission has determined that the Participants have sufficiently complied with the conditions set forth in the prior Orders and with the technical requirements for Quarterly Progress Reports set forth in section 6.6(c) of the CAT NMS Plan, including for purposes of determining compliance with any applicable Financial Accountability Milestones. The Commission makes no determination as to the veracity of the factual assertions made in Quarterly Progress Reports submitted pursuant to section 6.6(c) or as to whether the Participants have complied with the applicable Financial Accountability Milestones in all other respects. Moreover, the Commission makes no determinations with respect to the Full Implementation of CAT NMS Plan Requirements milestone described in section 1.1 of the CAT NMS Plan or the potential application of fee reduction provisions set forth in section 11.6 of the CAT NMS Plan with respect to that milestone. Rather, the Commission will consider the Participants' compliance with the CAT NMS Plan requirements, and/or compliance with the conditions set forth in the prior Orders and the impact of that compliance, in the context of fee proposals related to that milestone. Moreover, the Commission makes no determinations regarding the Participants' compliance or non-compliance with other provisions or requirements of the CAT NMS Plan that are not discussed in the prior Orders or in this Order.

[14] 15 U.S.C. 78mm(a)(1).

[15] 17 CFR 242.608(e).

[16] *See* 2022 Order, *supra* note 8.

[17] *See, e.g., id.* at 42248.

[18] *Id.*

difficulties that would otherwise be incurred by the Participants and Industry Members [19] that must fund the CAT. It also resolves the continued impasse over implementation of these aspects of the CAT, which impeded and distracted from these regulatory goals.

A. OTQT Performance Requirements

The Commission grants conditional exemptive relief from the OTQT performance requirements related to query response times and parallel processing of queries set forth in appendix D, section 8.1.2 of the CAT NMS Plan.[20] Such relief is subject to the following conditions:

- The OTQT must maintain or improve current functionality that enables requests for ''all related lifecycles'' to be made either prior to or after the generation of a parent query.
- The OTQT must further satisfy the performance parameters set forth in *Exhibit A.*
- The Plan Processor must continue to test the OTQT's performance with benchmark queries and evaluate the response times for actual queries on a monthly basis. Such tests and evaluations should contain at least the same content that is currently provided to Commission staff and should be provided to Commission staff and the Operating Committee within 30 days from the end of each month.
- The Plan Processor must conduct an annual concurrency test by launching 300 simultaneous query requests across the different query categories and measuring the response times against the applicable performance standards. The concurrency test shall be based on historical actual queries, and the mix of queries shall be based on the percentage of actual queries by category. The concurrency test attributes shall be provided in writing and reviewed in advance with Commission staff and the Operating Committee. The Participants must also provide the results of the annual concurrency testing performed by the Plan Processor on the OTQT to Commission staff within 30 days from the date of such testing. If the concurrency test response times do not satisfy the performance standards set forth in *Exhibit A* (*i.e.,* measured against a 90% compliance rate for each category, based on historical actual queries, with the mix of queries based on the percentage of actual queries by category), the Plan Processor shall promptly investigate and make recommendations to the Operating Committee for how to ensure adequate concurrency performance.
- The Plan Processor must establish policies and/or procedures requiring review of the OTQT's performance on a regular and ongoing basis and evaluation of opportunities for potential improvements to the OTQT's performance. The Participants must provide to Commission staff, on an annual basis, a written status update including information regarding any potential and actual implementation by the Plan Processor of improvements to the OTQT performance. The written status update shall also include an evaluation of (1) volume trends and projections; (2) usage patterns and types of queries performed; (3) response time statistics and trends; (4) outlier queries; (5) costs and benefits; and (6) regulatory need.

The Commission believes that this conditional exemptive relief reflects a reasonable compromise approach. The standards set forth in *Exhibit A* preserve, as a baseline, the OTQT functionality that is already in place, which should provide a measure of certainty for regulatory users regarding this query tool's expected performance. The other conditions set forth above enable better oversight of the OTQT's performance by the Participants and the Commission, which the Commission believes is in the public interest.

B. Requirements for Lifecycle Linkages Timeframes

The Commission grants conditional exemptive relief from the requirement set forth in appendix D, section 6.1 of the CAT NMS Plan that lifecycle linkages be created by T+1 at noon Eastern Time.[21] Such relief is subject to the following conditions:

- The Plan Processor must maintain or improve the existing performance of functionality currently providing lifecycle linkages for all order events by T+1 at 9 p.m. Eastern Time, except an interim CAT Order ID will not be required for Options Quotes once the functionality described below is implemented.
- The Plan Processor must develop and implement the functionality to provide a final CAT Order ID and lifecycle linkage for Options Quotes by T+2 at 8 a.m. Eastern Time, including all enrichments currently provided for such order events at T+5 at 8 a.m. Eastern Time. The Plan Processor will no longer be required to provide an interim CAT Order ID for Options Quotes once this functionality has been implemented. When late or corrected data is received for Options Quotes between T+1 at 8 a.m. Eastern Time and T+4 at 8 a.m. Eastern Time, the Plan Processor must run, on an ad hoc basis, a second processing cycle such that lifecycle linkage and all enrichments currently provided for such order events are performed by T+5 at 8 a.m. Eastern Time.

The Commission believes that this conditional exemptive relief facilitates settlement of the issues raised in the Participants' challenge to the 2022 order while preserving existing functionality for most types of order events.

C. Requirements for Re-Processing of Corrected Data Received After T+5 [22]

The Commission grants conditional exemptive relief from the re-processing requirements for corrected data received after T+5 that are set forth in appendix D, section 3 and section 6.2 of the CAT NMS Plan.[23] Such relief is subject to the following conditions:

- The Plan Processor must maintain its implementation of functionality related to late data lifecycle association that was approved by the Operating Committee on January 14, 2022 (the ''Late to the Lifecycle process'') and on September 20, 2022 (the ''Targeted Replay process'') (collectively, the ''Enhanced Late to the Lifecycle process''). Prior to the implementation of this functionality, in the limited circumstances in which there was a missing link between two disjoined segments of an order lifecycle, new or corrected data would join only one of the pre-existing segments and would be assigned to only one of the relevant

[19] ''Industry Member'' is defined in section 1.1 of the CAT NMS Plan as ''a member of a national securities exchange or a member of a national securities association.''

[20] The OTQT performance requirements set forth in appendix D, section 8.1.2 of the CAT NMS Plan are described in the 2022 Order. *See* 2022 Order, *supra* note 8, at 42248–50. The Commission understands that the Participants challenge the feasibility of strict compliance with these requirements.

[21] The lifecycle linkage performance requirements set forth in appendix D, section 6.1 of the CAT NMS Plan are described in the 2022 Order. *See* 2022 Order, *supra* note 8, at 42250–52. The Commission understands that the Participants challenge the feasibility of strict compliance with these requirements.

[22] For the purposes of this document, references to data received ''after T+5,'' or to post-T+5 data, submissions, or reports, are to data received ''after T+4 at 8 a.m. Eastern Time.''

[23] The T+5 re-processing requirements set forth in appendix D, section 3 and section 6.2 of the CAT NMS Plan are described in the 2022 Order. *See* 2022 Order, *supra* note 8, at 42252–53. The requirements concern how the CAT Order ID and other data elements (*e.g.,* sequence numbers, CAT Customer ID) are created for post-T+5 data, as well as any applicable impacts to those data elements for on-time data within the same lifecycle that were previously delivered to regulatory users on T+5. The Commission understands that the Participants challenge the feasibility of strict compliance with these requirements.

lifecycle CAT Order IDs for the disjoined segment and evaluated for further re-processing. Under the Enhanced Late to the Lifecycle process, all late records (*i.e.,* records received after T+5) include the date of the correction and, if applicable, the record identifier of the record being corrected as part of normal re-processing. In addition, the late record is now associated with all relevant lifecycles as part of normal re-processing, such that order event lifecycles may now be associated with more than one CAT Order ID.

- The Participants must approve a change order to adopt the below-described functionality no later than 30 days following the effective date of this Order:
  - Functionality that creates a lifecycle mapping which indicates all lifecycle associations made during the Enhanced Late to the Lifecycle process;
  - Functionality that presents to regulatory users post-T+5 data in a manner substantially similar to how such data would have been represented if it had been reported prior to T+5, including by replicating and replaying records with enrichments impacted by post-T+5 submissions, creating updated enrichments, and persisting the replicated records within the underlying data (the ''Full Replay process''); and
  - Functionality that enhances the OTQT, including the ability to include or exclude any records that were created or replaced as a result of the Full Replay process.

Such functionality must be fully implemented and made available to regulatory users within twelve months of the change order's approval by the Participants.

- The Plan Processor must schedule the Enhanced Late to the Lifecycle process and the Full Replay process to run weekly, such that late reported data received through Friday of the prior week are available for regulatory users on the following business day at 8 a.m. Eastern Time, absent extraordinary circumstances, for data within the prior 18 months. For data outside of this 18-month window, the Participants must schedule the Enhanced Late to the Lifecycle process and the Full Replay process to run no less frequently than quarterly.

The Commission understands that this alternative technological solution, when fully implemented, will meaningfully advance the regulatory goals of Rule 613 and the CAT NMS Plan by enabling regulatory users to view corrected data that is submitted after T+5 as part of an order event lifecycle (which may be represented by more than one CAT Order ID) and in a manner that does not require such regulatory users to know whether late records were submitted and/or to perform additional query steps to obtain the most up-to-date records. The Commission believes this alternative technological solution will help regulatory users to better understand the impact of post-T+5 reports.

D. Requirements for SIP Data Linkage

The Commission grants conditional exemptive relief from the SIP Data linkage requirements that are set forth in section 6.5(b)(i) and appendix D, section 3 of the CAT NMS Plan.[24] Such relief is subject to the following conditions:

- The Plan Processor must continue to provide regulatory users with the side-by-side view of SIP Data and other transactional data in the same format and manner that is currently available in the OTQT.[25]

This functionality requires regulatory users to manually match SIP Data with other transactional data reported to the CAT. However, the Commission believes this is an acceptable alternative solution that will continue to make available SIP Data to regulatory users while facilitating settlement of the issues raised in the Participants' challenge to the 2022 Order.

E. Reporting Requirements for Port-Level Settings

The Commission grants conditional exemptive relief from the requirements as applied to port-level settings that are set forth in Rule 613(c)(7) and sections 6.3(d)(i)(F), 6.3(d)(ii)(G), 6.3(d)(iii)(F), 6.3(d)(iv)(E), and 6.4(d)(i) of the CAT NMS Plan for the following special handling instructions described in the current CAT Industry Member Technical Specifications that may be set by Industry Members at the various Participant exchanges via exchange ports (the ''Exempted Port-Level Settings''): [26]

ATT	Attributable. Order is routed to an exchange or ATS with instructions that the order is attributable.
DNI	Do Not Increase.
DNR	Do Not Reduce.
DNRT	Do Not Route.
RLO	Retail Liquidity Order.
STP	Self Trade Prevention.

Under the conditional exemptive relief granted herein, the Participants will not be required to obligate Industry Members to report these six special handling instructions when an Industry Member routes an order to a national securities exchange over an exchange port that is configured for one of these special handling instructions.[27]

This conditional exemptive relief applies only when the Exempted Port-Level Settings are set at the port-level at a national securities exchange. Aside from the Exempted Port-Level Settings, this Order does not provide exemptive relief from the reporting requirements set forth in the CAT NMS Plan for any existing and/or new special handling instructions that may be set at the port-level at a national securities exchange and that may constitute Material Terms of the Order; likewise, this Order does not provide exemptive relief for any Material Terms of the Order that are set at the port-level on Industry Member alternative trading systems or broker-dealer port-level settings. To the extent that the Participants and/or Industry Members wish to receive similar exemptive relief related to other Material Terms of the Order set at the

[24] The SIP Data linkage requirements set forth in section 6.5(b)(i) and appendix D, section 3 of the CAT NMS Plan is described in the 2022 Order. *See* 2022 Order, *supra* note 8, at 42253–54. The Commission understands that the Participants challenge the feasibility of strict compliance with these requirements.

[25] This ''side-by-side'' functionality refers to the ability for users of the OTQT to include SIP Data in multi-object searches that include transactional data from Industry Member and Plan Participant CAT Reporters. For example, a regulatory user may elect to query Exchange Equity Events and SIP Trades simultaneously for trades in a given security; the results will be returned interweaved within a single result set, in a logical sequence.

[26] The requirements as applied to port-level settings set forth in in Rule 613(c)(7) and sections 6.3(d)(i)(F), 6.3(d)(ii)(G), 6.3(d)(iii)(F), 6.3(d)(iv)(E), and 6.4(d)(i) of the CAT NMS Plan are described in the 2022 Order. *See* 2022 Order, *supra* note 8, at 42254–55. The Commission understands that, notwithstanding this Order, the Participants continue to disagree with its interpretation of these requirements and challenge the feasibility of strict compliance with these requirements, other than with respect to the Exempted Port-Level Settings. This Order does not resolve (or have any bearing on) the parties' remaining interpretive disagreement on this issue, but instead provides exemptive relief that renders resolution of the issue unnecessary as to all port-level settings other than the Exempted Port-Level Settings.

[27] As explained in the 2022 Order, the CAT NMS Plan does not require all port-level settings to be reported to the CAT. Rule 613 and the CAT NMS Plan only require Participants and Industry Members to report port-level settings that are used by a sender or a receiver of an order to communicate the Material Terms of the Order, including ''any special handling instructions.'' Furthermore, Rule 613 and the CAT NMS Plan only obligate the sender of an order to report the Material Terms of the Order that it communicated to and/or agreed upon with the receiver of the order, including default or implicit special handling instructions communicated through a port-level setting. If the receiver of an order subsequently attaches ''any special handling instructions'' to an order without informing the sender, including special handling instructions communicated through a port-level setting, only the receiver would be obligated to report those Material Terms of the Order.

port-level, they must submit an exemptive relief request to the Commission for its consideration.

Such relief is subject to the following conditions:

- The Participants must report the Exempted Port-Level Settings in the order receipt record, regardless of whether such Exempted Port-Level Settings are ''triggered'' or ''applied.'' [28]
- The Participants must maintain and communicate to Industry Members via a CAT Alert a mapping of each exchange-specific port-level setting related to the Exempted Port-Level Settings, substantially in the form of the draft mapping the Participants have provided to the Commission.[29]

The Commission believes that this alternative technological solution, when fully implemented, reflects a reasonable compromise approach with respect to a limited set of data.[30]

F. Requirements for Lifecycle Linkages Between Customer Orders and ''Representative'' Orders

The Commission grants temporary conditional exemptive relief from the requirements set forth in appendix D, section 3 of the CAT NMS Plan related to lifecycle linkages between customer orders and representative orders until January 31, 2025.[31] Such relief is intended to mirror the exemptive relief provided by the 2023 Order and is subject to the following condition:

- The Participants must require Industry Members to report ''representative'' orders as currently described in FAQs F5–F7 and as described in other exemptive relief issued by the Commission by January 31, 2025.[32]

The Commission believes that the relief provided in the 2023 Order gives Industry Members sufficient time to make any necessary systems changes to implement the required functionality, especially because the technical specifications and/or scenarios documents relating to the reporting and linkage of all ''representative'' orders have already been promulgated by the Participants. Therefore, the Commission does not believe it is necessary to issue any additional extension of exemptive relief in connection with these requirements.

G. Requirements for Participant Reporting of Rejected Orders

The Commission grants conditional exemptive relief from the requirements set forth in Rule 613(c)(7) and section 6.3(d)(i) and appendix D, section 3 of the CAT NMS Plan relating to Participant reporting of rejected orders and subsequent linkage of such orders.[33] Such relief is subject to the following conditions:

- The Participants must maintain or improve their existing reporting of orders that are received and subsequently rejected, including maintenance by Participants of any existing reporting or linkage of the keys necessary for the linkage processing specified below. The Plan Processor must maintain its existing validations of such orders.
- The Participants must approve a change order to adopt the below-described functionality no later than 60 days following the effective date of this Order:
  - Functionality that will attempt ''forward lifecycle linkage'' processing, including all enrichments currently provided for other order events, of Industry Member MEOR, MOOR, and MEMR Order Route events containing a routeRejectedFlag populated as ''true'' with their corresponding Participant Reject Message events described in the Participant Technical Specifications in instances where the keys necessary for such linkage are available (*i.e.,* Symbol (or Option ID), RoutingParty, RoutedOrderID, Session).[34]

Such functionality must be fully implemented and made available to regulatory users within twelve months of the change order's approval by the Participants.

The Commission understands that this alternative technological solution, when fully implemented, will meaningfully advance the regulatory goals of Rule 613 and the CAT NMS Plan by providing regulatory users with additional information about rejected orders.

III. Conclusion

Accordingly, *it is hereby ordered,* pursuant to section 36(a)(1) of the Exchange Act [35] and Rule 608(e) under the Exchange Act,[36] that the above-described conditional exemptive relief be granted, effective immediately upon the date of issuance of an order by the D.C. Circuit dismissing the Participants' petition for review of the 2022 Order.

By the Commission.

Sherry R. Haywood,

Assistant Secretary.

Exhibit A

Online Targeted Query Tool Performance Parameters

1. *General:* Subject to the specific conditions described in this *Exhibit* A, OTQT performance must satisfy both (i) an operational completion rate (measuring the successful completion of all attempted queries), and (ii) a query compliance rate (measuring the response time performance of all successfully completed queries).

2. *Operational Completion Rate:* Queries will be subject to a 95% operational completion rate measured quarterly against

[28] The Commission understands that the Participants disagree with its interpretation that special handling instructions that are never ''triggered'' or ''applied'' to an order qualify as Material Terms of the Order with respect to any other existing and/or new special handling instructions that may be set at the port-level at a national securities exchange.

[29] There are differences between the technical specifications utilized by Industry Members and Participants, as well as differences in reporting among the Participants. While the Participants may update this mapping for the Exempted Port-Level Settings as needed, new Material Terms of the Order that are set at the port-level and that are not specifically addressed this Order may not be added to this mapping without additional exemptive relief from the Commission.

[30] The Commission notes that its analysis is specific to the Exempted Port-Level Settings and reserves judgment as to whether the above-described alternative technological solution would be appropriate for any other Material Terms of the Order that are communicated via a port-level setting.

[31] The requirements related to lifecycle linkages between customer orders and representative orders set forth in appendix D, section 3 of the CAT NMS Plan are described in the 2022 Order. *See* 2022 Order, *supra* note 8, at 42255–56.

[32] *See, e.g.,* Securities Exchange Act Release No. 88702 (Apr. 20, 2020), 85 FR 23075 (Apr. 24, 2020); 2022 Order, *supra* note 8, at 42255–56. *See also* FAQ F5–F7, *available at https://catnmsplan.com/faq.*

[33] The requirements related to Participant reporting of rejected orders set forth in Rule 613(c)(7) and section 6.3(d)(i) and appendix D, section 3 of the CAT NMS Plan are described in the 2022 Order. *See* 2022 Order, *supra* note 8, at 42256–57. The Commission understands that, notwithstanding this Order, the Participants continue to disagree with its interpretation of these requirements and challenge the feasibility of strict compliance with that interpretation. This Order does not resolve the parties' interpretive disagreement on this issue, but instead provides exemptive relief that renders resolution of the issue unnecessary.

[34] The ''forward lifecycle linkage'' processing referred to above is intended to capture functionality that the Participants believe may be feasible in light of a study of recent data. Based on that study and based on current trading volume market share among the various Participant exchanges, the Plan Processor currently estimates that approximately 90% of Industry Member MEOR, MOOR, and MEMR Order Route events containing a routeRejectedFlag populated as ''true'' may be programmatically linked with their corresponding Participant Reject Message events. For the avoidance of doubt, for purposes of satisfying the conditions of this Order, the Participants will not be required to modify their existing architectures or reporting and will not be required to provide ''reverse linkage'' of Participant Reject Message events to Industry Member Order Route events. Moreover, this Order does not impose any required minimum linkage rate as a condition to exemptive relief. Linkage errors relating to rejected orders will not be required to be included in compliance error rates.

[35] 15 U.S.C. 78mm(a)(1).

[36] 17 CFR 242.608(e).

all attempted queries in the aggregate. The operational completion rate will measure the successful completion of all attempted queries, excluding failed queries resulting from a service interruption experienced by the Plan Processor's cloud service provider.

3. *Query Compliance Rate.* Queries will be subject to a 90% query compliance rate measured monthly against all actual query results based on the categories and response times set forth below. The query compliance rate will measure the response time performance of all successfully completed queries for each category. Response times shall be measured from the time of query submission by the regulatory user to the time that the results are available to the regulatory user (*i.e.,* including the time required to formulate a data mart).

Category	Response time (minutes)	Description
OLA Viewer	2	
Standard Queries		
Small	10	See data objects below.
Medium	30	See data objects below.
Large	60	See data objects below.
Complex	240	• More than one trade date or object, or • Returns more than 1M rows.
All Related Lifecycles [37]		
Simple	20	• Fewer than 10,000 lifecycles, and • Single-day lifecycle count.
Complex	720	• Fewer than 50,000 lifecycles, and • Fewer than 60 lifecycle dates.

STANDARD QUERY DATA OBJECTS [38]

Small (10 minutes)	Medium (30 minutes)	Large (60 minutes)
Corporate Actions	Equity Exchange Events	IM Equity Events.
Equity Member Dictionary	Exchange Orders	Options Exchange Events.
Equity Off Exchange Events	IM Options Events	Options NBBO.
Equity Symbol Master	Market Participant Quotes	Options Orders/Trades.
Equity Trade Events	Options Quotes	OPRA RAW.
FDID CCID Map	SIP Quotes.	
IDQS BBO		
Market Maker Dictionary		
OCC Options Product		
OCC Options Series		
Off Exchange Trade Events		
Off Exchange Trades		
Options Dictionary		
Options Member Dictionary		
Options Trade Events		
OTC Halt Events		
Self Help Declaration Events		
SIP Admin		
SIP CTA Admin Messages		
SIP CTS Trade Summary		
SIP CTS Trades		
SIP Issue Status		
SIP MWCB Status		
SIP OTC Halts		
SIP Quote Events		
SIP Summary		
SIP Trades		
SIP UTP Admin Messages		
SIP UTP LULD Price Band		
SIP UTP Trade Prior Day As-Of		
SIP UTP Trade Summary		
SIP UTP Trades		

4. *Reporting Requirements.* The Plan Processor shall provide a monthly report noting (i) the operational completion rate for all attempted queries in the aggregate, and (ii) the query compliance rate for each category described above, to Commission staff within 30 days from the end of each month.

5. *Reasonable Adjustment Period.* In order to permit the Plan Processor to promptly scale up the OTQT to ensure adequate system capacity in the event of significant, unanticipated, or rapid changes in data volumes and/or user behavior that require application coding changes and/or changes to how historical data is stored, response times shall be subject to a reasonable adjustment period, (i) not to exceed 60 days for items

[37] For an all related lifecycles request made prior to the generation of a parent query, the time of query submission will not commence until completion of the parent query.

[38] If a new data object is created in the future, the Plan Processor will undertake a six-month assessment period (commencing once the data object is populated with actual data) to understand volumes and regulatory usage and, based on these observations, will slot the new data object into one of these existing categories.

requiring application coding changes,[39] and (ii) not to exceed 120 days for items requiring changes to how a data object is stored and that may include changes impacting historical data in the object. These 60-day and 120-day periods shall be measured from the date on which the monthly compliance report is provided to Commission staff. For purposes of this condition:

- A significant, unanticipated, or rapid change in data volume shall be deemed to have occurred in the event of an average daily data volume increase of 30% in the applicable data object(s) from the lesser of: (i) the peak daily data volume observed in the prior month, or (ii) the peak daily data volume observed in the same month in the prior year.
- A significant, unanticipated, or rapid change in user behavior shall be deemed to have occurred in the event of an average daily OTQT query count increase of 30% from the lesser of: (i) the peak daily OTQT query count observed in the prior month, or (ii) the peak daily OTQT query count observed in the same month in the prior year.

Written notification of these determinations will be provided to and reviewed with Commission staff.

[FR Doc. 2023–24624 Filed 11–7–23; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20018 and #20019; ILLINOIS Disaster Number IL–20001]

Administrative Disaster Declaration of a Rural Area for the State of Illinois

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative disaster declaration of a rural area for the State of Illinois dated 11/02/2023.

Incident: Severe Storms and Flooding.

Incident Period: 06/29/2023 through 07/02/2023.

DATES: Issued on 11/02/2023.

Physical Loan Application Deadline Date: 01/02/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 08/02/2024.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan 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 disaster declaration of a rural area, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Hancock, Sangamon, Vermilion, Washington

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.000
Homeowners without Credit Available Elsewhere	2.500
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
For Economic Injury:	
Business 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 physical damage is 200186 and for economic injury is 200190.

The State which received an EIDL Declaration is Illinois.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2023–24682 Filed 11–7–23; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20060 and #20061; TENNESSEE Disaster Number TN–20002]

Administrative Declaration of a Disaster for the State of Tennessee

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Tennessee dated 11/02/2023.

Incident: Severe Storms, Straight-line Winds and Tornadoes.

Incident Period: 08/07/2023.

DATES: Issued on 11/02/2023.

Physical Loan Application Deadline Date: 01/02/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 08/02/2024.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan 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 disaster declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Knox.

Contiguous Counties:

Tennessee: Anderson, Blount, Grainger, Jefferson, Loudon, Roane, Sevier, Union

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.000
Homeowners without Credit Available Elsewhere	2.500
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
For Economic Injury:	
Business 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 physical damage is 20060C and for economic injury is 200610.

[39] Application coding changes are changes requiring a software release and deployment. For the avoidance of doubt, adding/removing system capacity or the incremental size of capacity changes (*e.g.,* autoscaling compute node step size) within the limits of the OTQT system are configuration changes and are not considered application coding changes.

The States which received an EIDL Declaration are Tennessee.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2023–24680 Filed 11–7–23; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20026 and #20027; FLORIDA Disaster Number FL–20000]

Administrative Declaration of a Disaster for the State of Florida

AGENCY: U.S. Small Business Administration.

ACTION: Correction.

SUMMARY: This is a correction to an Administrative declaration of a disaster for the State of Florida dated 10/30/2023.

Incident: Tornado.

Incident Period: 10/12/2023.

DATES: Issued on 11/02/2023.

Physical Loan Application Deadline Date: 12/29/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 07/30/2024.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan 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: Correction is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Citrus.

Contiguous Counties:

Florida: Hernando, Levy, Marion, Sumter

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.000
Homeowners without Credit Available Elsewhere	2.500
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
For Economic Injury:	
Business 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 physical damage is 20026C and for economic injury is 200270.

The State which received an EIDL Declaration is Florida.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2023–24683 Filed 11–7–23; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 12258]

Notice of Determinations; Culturally Significant Object Being Imported for Exhibition—Determinations: ''Reclaiming El Camino: Native Resistance in the Missions and Beyond'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object being imported from abroad pursuant to an agreement with its foreign owner or custodian for temporary display in the exhibition ''Reclaiming El Camino: Native Resistance in the Missions and Beyond'' at the Autry Museum of the American West, Los Angeles, California, and at possible additional exhibitions or venues yet to be determined, is of cultural significance, and, further, that its temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2023–24653 Filed 11–7–23; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 12256]

60-Day Notice of Proposed Information Collection: Shrimp Exporter's/Importer's Declaration

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *January 8, 2024.*

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

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2023–0036'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: DS2031@state.gov*
- *Regular Mail:* Send written comments to: Office of Marine Conservation (OES/OMC), Attn: Section 609 Program, 2201 C Street NW, Room 2758, Washington, DC 20520–2758

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Shrimp Exporter's/Importer's Declaration.
- *OMB Control Number:* 1405–0095.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Oceans and International Environmental and Scientific Affairs, Office of Marine Conservation (OES/OMC).
- *Form Number:* DS–2031.
- *Respondents:* Business or other for-profit organizations.
- *Estimated Number of Respondents:* 3,000.
- *Estimated Number of Responses:* 10,000.
- *Average Time per Response:* 10 minutes.
- *Total Estimated Burden Time:* 1,666 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The DS–2031 form is necessary to document imports of shrimp and products from shrimp pursuant to the State Department's implementation of Section 609 of Public Law 101–162, which prohibits the entry into the United States of shrimp harvested in ways which are harmful to sea turtles. Respondents are exporters of shrimp and products from shrimp and government officials in countries that export shrimp and products from shrimp to the United States. The importer is required to present the DS–2031 form at the port of entry into the United States, to retain the DS–2031 form for a period of three years subsequent to entry, and during that time to make the DS–2031 form available to U.S. Customs and Border Protection or the Department of State upon request.

Methodology

The DS–2031 form is completed by the exporter, the importer, and under certain conditions a government official of the harvesting country. The DS–2031 form accompanies shipments of shrimp and shrimp product to the United States and is to be made available to U.S. Customs and Border Protection at the time of entry and for three years after entry.

Mahlet N. Mesfin,

Deputy Assistant Secretary for Oceans, Fisheries, and Polar Affairs, Department of State.

[FR Doc. 2023–24688 Filed 11–7–23; 8:45 am]

BILLING CODE 4710–09–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 1st quarter of FY 2024, and other business.

DATES: The SJI Board of Directors will be meeting on Monday, December 4, 2023 at 1 p.m. ET.

ADDRESSES: SJI Headquarters, 12700 Fair Lakes Circle, Suite 340, Fairfax, Virginia.

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. 2023–24695 Filed 11–7–23; 8:45 am]

BILLING CODE 6820–SC–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 578X]

Austin Area Terminal Railroad, Inc—Discontinuance of Service Exemption—In Bastrop, Burnet, Lee, Llano, Travis, and Williamson Counties, Texas

On December 30, 2022, the Board, by decision of the Director of the Office of Proceedings (Director), rejected the verified notice of exemption filed by Austin Area Terminal Railroad, Inc. (AATR) to discontinue service over an approximately 162-mile line in Texas because the required certification concerning the absence of local traffic on the line was deficient. AATR appealed that decision. For the reasons discussed below, the Board will deny the appeal. Nevertheless, the Board will grant on its own motion an exemption under 49 U.S.C. 10502 from the prior approval requirements of 49 U.S.C. 10903 permitting AATR to discontinue common carrier rail service over the line.

Background

On November 30, 2022, AATR filed a verified notice of exemption under 49 CFR 1152.50 to discontinue common carrier rail service over approximately 162 miles of rail line owned by Capital Metropolitan Transportation Authority, located between milepost AUNW–MP 0.0 (SPT–MP 57.00), west of Giddings, and milepost AUNW–MP 154.07 (SPT–MP 99.04), at Llano, including the Marble Falls Branch (6.43 miles), the Scobee Spur (3.3 miles), and the Burnet Spur (0.93 miles) in Bastrop, Burnet, Lee, Llano, Travis, and Williamson Counties, Tex. (the Lines).

According to AATR, it received Board authority to provide common carrier service over the Lines in 2002, replacing its parent company, Trans-Global Solutions Inc., as operator. *See Austin Area Terminal R.R.—Change in Operators Exemption—Trans-Glob. Sols., Inc.,* FD 33972 (STB served Dec. 20, 2000); *see also Trans-Glob. Sols., Inc.—Operation Exemption—Cap. Metro. Transp. Auth.,* FD 33860 (STB served Apr. 4, 2000). AATR's verified notice states, however, that it has not operated over the Lines in many years and that the Lines are presently operated by Austin Western Railroad, L.L.C. (AWRR), a rail carrier unaffiliated with AATR. (Verified Notice 1–2.) [1]

On December 30, 2022, the Director rejected the notice, noting that, under 49

[1] *See Austin W. R.R.—Operation Exemption—Cap. Metro. Transp. Auth.,* FD 35072 (STB served Sept. 14, 2007).

CFR 1152.50(b), ''[a]n abandonment or discontinuance of service or trackage rights is exempt if the carrier certifies that no local traffic has moved over the line for at least 2 years . . . .'' The Director observed that, although AATR certified that *it* had not provided service over the Lines for at least two years, AATR also noted that the Lines were ''presently operated'' by AWRR. *Austin Area Terminal R.R.—Discontinuance of Service Exemption—in Bastrop, Burnet, Lee, Llano, Travis, & Williamson Cntys., Tex.,* AB 578X, slip op. at 1 (STB served Dec. 30, 2022). Thus, because AATR had not certified that there had been *no* local traffic on the Lines during the preceding two years, the Director found that the verified notice did not meet the requirements of the two-year out-of-service provision at 49 CFR 1152.50.

On appeal, AATR argues, among other things, that granting its appeal would be consistent with certain agency precedent accepting carrier-specific, two-year-out-of-service certifications—allowing invocation of the discontinuance class exemption when a carrier has certified that it has handled no traffic (local or otherwise) for at least two years, regardless of whether the line in question has hosted common carrier operations by other railroads in the past two years. (AATR Appeal 6.) AATR further asserts that not allowing carrier-specific certifications would unnecessarily increase regulatory barriers to industry exit and, in turn, would discourage honest and efficient management of railroads, contrary to the objectives of 49 U.S.C. 10101(7) and (9).[2] (AATR Appeal 10.)

Discussion and Conclusions

Under 49 CFR 1011.7(a)(2)(x), the Board has delegated to the Director the authority to determine whether to issue notices of exemption. The Board, however, has reserved for itself the consideration and disposition of all appeals of initial decisions issued by the Director. *See* 49 CFR 1011.2(a)(7). In this proceeding, AATR argues that the Director erred in rejecting its verified notice of exemption. On appeal, the Board considers whether the notice was properly rejected under the circumstances presented. *See, e.g., Ill. Cent. R.R.—Aban. Exemption—in Champaign Cnty., Ill.,* AB 43 (Sub-No. 189X), slip op. at 3 (STB served July 2, 2015).

The Board finds that the verified notice was properly rejected. First, the Director's application of 49 CFR 1152.50(b) is consistent with the literal language of the regulation, which states that ''[a]n abandonment or discontinuance of service or trackage rights is exempt if the carrier certifies that *no local traffic* has moved over the line for at least 2 years . . . .'' (emphasis added). Indeed, the final rule adopting the discontinuance class exemption noted that the meaning of ''out of service'' for the purpose of that exemption is the same as in the rulemaking establishing the class exemption for abandonments. *Exemption of Out of Serv. Rail Lines (Discontinuance of Serv. & Trackage Rts.),* 1 I.C.C.2d 55, 56 (1984). The abandonment rulemaking defined ''out of service'' rail lines as those lines where there had been ''*no* traffic originating or terminating on the line for at least 2 years.'' *Exemption of Out of Serv. Rail Lines,* 366 I.C.C. 885, 887 (1983) (emphasis added). Further, the final rule adopting the discontinuance class exemption noted that such discontinuances were limited in scope, having ''little or no competitive or operational impact,'' because they ''w[ould] usually pertain to short-line segments with *no* shippers,'' and that regulation was ''not needed to protect shippers from the abuse of market power, because the lines *would not have been used by shippers* for at least 2 years.'' *Exemption of Out of Serv. Rail Lines (Discontinuance of Serv. & Trackage Rights),* 1 I.C.C.2d at 57 (emphasis added).

The Director's ruling was also consistent with the discussion in *CSX Transportation in Jefferson & Indiana Counties, Pa.,* AB 55 (Sub-No. 453X) (ICC served Nov. 27, 1992), cited by the Director in the challenged order. There, the agency explained that the ''test [under the regulation] is not whether [the discontinuing carrier] has provided any local service over the line in the past 2 years but whether there has been any local service on the line during that period.'' *CSX Transp.,* AB 55 (Sub-No. 453X), slip op. at 2.[3] Although AATR characterizes *CSX Transportation* as ''obscure,'' (AATR Appeal 6), in none of the cases AATR cites did the agency squarely address the issue here: whether the regulation requires the discontinuing carrier to certify that no local traffic at all—as opposed to just its own—has moved over the line for at least two years. Nor did any party in the decisions cited by AATR challenge the adequacy of a carrier-specific certification versus one covering all local traffic on the line.[4]

The Board acknowledges that carrier-specific certifications in two-year-out-of-service discontinuance proceedings have been more recently accepted without challenge or controversy. *See, e.g., Minn. Com. Ry.—Discontinuance of Trackage Rts. Exemption—in Anoka, Hennepin, Ramsey, & Wash. Cntys., Minn.,* AB 882 (Sub-No. 4X) (STB served May 20, 2020); *Wheeling & Lake Erie Ry.—Discontinuance of Serv. Exemption—in Erie Cnty., Ohio,* AB 227 (Sub-No. 13X) (STB served Mar. 22, 2019); *All. Terminal R.R.—Discontinuance of Serv. & Discontinuance of Trackage Rts. Exemption—in Denton & Tarrant Cntys., Tex.,* AB 1262X (STB served Apr. 23, 2018). Moreover, as the Board has explained previously, discontinuance of trackage rights that have not been operated for at least two years is unlikely to negatively impact shippers, ''especially . . . because a discontinuance of trackage rights still leaves [at least the] line owner in place to conduct service.'' *See Norfolk S. Ry.—Acquis. & Operation—Certain Rail Lines of the Del. & Hudson Ry.,* FD 35873, slip op. at 20 (STB served May 15, 2015).

Nevertheless, to resolve the inconsistency, the Board clarifies that the regulation should be applied as written and as intended at the time of its adoption. Carriers using the two-year-out-of-service notice must certify that *no local traffic* has moved over the line for two years, not just their own traffic. The Board further notes that carriers may petition for individual exemptions under 49 U.S.C. 10502(a). While the individual exemption process

[2] AWRR and its parent company, Watco Holdings, Inc., filed a joint pleading on January 20, 2023, confirming AWRR's role providing common carrier service on the Lines and noting their general support for AATR's discontinuance efforts.

[3] The ICC later acknowledged the findings in *CSX Transportation* in a subsequent decision by the entire Commission. *See Buffalo & Pittsburgh R.R.—Discontinuance & Aban. Exemption—Between DC Tower & Homer City, in Jefferson & Ind. Cntys., Pa.,* AB 369 (Sub-No. 2X) et al., slip op. at 2 n.3 (ICC served Nov. 17, 1993) (explaining that the notice in *CSX Transportation* was ''rejected because CSXT had failed to certify that there was no local traffic on the Line'').

[4] AATR notes that in *Delaware & Hudson Railway—Discontinuance of Trackage Rights Exemption—in Broome County, N.Y.,* AB 156 (Sub-No. 27X) (STB served Oct. 18, 2016), the Board rejected several challenges to the notice of exemption, ''including one focused on the accuracy of [the carrier's] certification.'' (AATR Appeal 9.) Questions were raised in that proceeding about whether the discontinuing carrier had in fact conducted local traffic on the relevant lines in the last two years. *See, e.g.,* Reply to D&H Reply to Pet. to Revoke at 7, May 12, 2015, *Del. & Hudson,* AB 156 (Sub-No. 27X) (arguing that if any of the traffic that ''D&H carries'' on the trackage rights lines is local traffic, then the ''Exemption Notice fails''). But no party in *Delaware & Hudson* argued that carrier-specific certifications, in general, do not qualify for the class exemption, and the Board accepted the certification there—as it did in all the decisions cited by AATR—without discussing the issue raised in the Director's order or in *CSX Transportation.*

is less streamlined than the class exemption procedures, it still provides an avenue for obtaining ''expedite[d] decisions'' with ''minimize[d] regulatory burdens'' in uncontested or noncontroversial proceedings involving rail line abandonments and discontinuances. *See, e.g., Minn. N. R.R.—Aban. Exemption—Between Redland Junction & Fertile, in Polk Cnty., Minn.,* AB 497 (Sub-No. 2X), slip op. at 11 n.17 (STB served Nov. 14, 1997) (''Detailed revenue and cost analysis is generally reserved for the application process . . . .'') Indeed, the Board has readily granted petitions for exemption to discontinue unused trackage rights in appropriate circumstances where there would be no impact on service. *See, e.g., Idaho N. & Pac. R.R.—Discontinuance of Trackage Rts. Exemption—in Canyon, Payette, & Wash. Cntys.,* AB 433 (Sub-No. 4X) (STB served Jan. 3, 2013) (granting discontinuance authority for one set of overhead trackage rights that had not been used for 17 years, and another that had not been used for three years); *BNSF Ry.—Discontinuance of Trackage Rts.—in Peoria & Tazewell Cntys., Ill.,* AB 6 (Sub-No. 470X) (STB served June 4, 2010) (granting discontinuance authority for overhead trackage rights that had not been used in 28 years).

Therefore, based upon the foregoing, AATR's appeal of the Director's decision rejecting the notice of exemption will be denied. However, as discussed below, the Board will grant on its own motion the discontinuance of rail service by AATR over the lines at issue.

The Sua Sponte Exemption

In rejecting a verified notice of exemption, the Board often requires or suggests that a party file an application or petition for exemption to obtain the necessary authority it seeks. Under the circumstances here, however, and given the sufficiency of the current record, the Board will minimize the burden on AATR by granting an exemption for discontinuance authority over the Lines sua sponte.

Under 49 U.S.C. 10903, a rail carrier may not discontinue operations without the Board's prior approval. Pursuant to 49 U.S.C. 10502(a), however, the Board shall, to the maximum extent possible, exempt a transaction or service from regulation upon finding that (1) regulation is not necessary to carry out the rail transportation policy (RTP) of 49 U.S.C. 10101, and (2) either (a) the transaction or service is of limited scope, or (b) regulation is not needed to protect shippers from the abuse of market power.

Here, detailed scrutiny under 49 U.S.C. 10903 of discontinuance by AATR is not necessary to carry out the rail transportation policy. By minimizing the administrative expense of the application or petition process, an exemption would reduce regulatory barriers to exit. *See* 49 U.S.C. 10101(2), (7), (15). An exemption would also encourage efficient management by relieving AATR of the responsibility of operating over rail lines it has not used in more than 15 years. *See* 49 U.S.C. 10101(9). Further, other aspects of the RTP would not be adversely affected.

Regulation of the proposed discontinuance is also not needed to protect shippers from the abuse of market power.[5] AATR has not operated over the Lines in many years, and shippers may request service from AWRR, which offers common carrier service over the Lines.

Employee Protection. Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a carrier of its statutory obligation to protect the interests of its employees. Accordingly, as a condition to granting this exemption, the Board will impose the employee protective conditions set forth in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

Offers of Financial Assistance, Interim Trail Use/Rail Banking, Public Use, and Environmental Review. Typically, in individual exemption proceedings, formal expressions of intent to file an offer of financial assistance (OFA) to subsidize continued rail service are due within 10 days of the **Federal Register** publication giving notice of the petition for exemption. *See* 49 CFR 1152.27(c)(1)(i). These filings must indicate the intent to file an OFA for subsidy and demonstrate that the filers are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i). In this case, given the Board's sua sponte grant of an exemption, formal expressions of intent must be filed by November 13, 2023.

Provided no formal expression of intent to file an OFA to subsidize continued rail service has been received, this exemption will be effective on December 3, 2023, unless stayed pending reconsideration. And, because this is a discontinuance and not an abandonment, the Board need not consider OFAs to acquire the Lines, interim trail use/rail banking requests under 16 U.S.C. 1247(d), or requests to negotiate for public use of the Lines under 49 U.S.C. 10905. Lastly, because there will be an environmental review if abandonment is sought in the future, environmental review is unnecessary here.

In sum, the Board permits the discontinuance of rail service by AATR over the above-described rail lines, and notice of AATR's exemption will be published in the **Federal Register**.

It is ordered:

1. AATR's appeal of the Director's decision is denied.

2. Under 49 U.S.C. 10502, the Board exempts from the prior approval requirements of 49 U.S.C. 10903 the discontinuance of service by AATR on the above-described lines, subject to the employee protective conditions in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

3. Notice of the exemption will be published in the **Federal Register**.

4. This exemption will be effective December 3, 2023.

5. Formal expressions of intent to file an offer of financial assistance (OFA) to subsidize continued rail service are due November 13, 2023.

6. Petitions to reopen and petitions to stay the effectiveness of the exemption must be filed by November 20, 2023.

7. This decision is effective on its service date.

Decided: November 2, 2023.

By the Board, Board Members Fuchs, Hedlund, Oberman, Primus, and Schultz. Board Member Fuchs concurred with a separate expression.

BOARD MEMBER FUCHS, concurring:

I agree with today's decision (Decision) that the Director's interpretation of ''no local traffic''—requiring a line-specific certification—is consistent with the plain meaning of the regulation, Decision 3, and supported by the relevant legal history.[1] I write

[5] Given the Board's finding regarding market power, it need not be determined whether the proposed discontinuance is limited in scope.

[1] The Decision accurately traces the relationship of the discontinuance rulemaking to the abandonment rulemaking, and it faithfully quotes multiple statements in the discontinuance rulemaking preamble that treat phrases such as ''out of service'' and ''no local traffic'' as applying to all carriers on the line, not just the filing carrier. Decision 3. Yet I am troubled that the **Federal Register** notices accompanying the proposed and final rules in the discontinuance proceeding state the exemption can apply when ''no traffic has been handled locally on the line *by the carrier seeking the discontinuance* for at least 2 years.'' *Exemption of Out of Service Lines (Discontinuance of Service and Trackage Rights),* 48 FR 27584 (June 16, 1983) (emphasis added). Ultimately, I find **Federal Register** notices contain a drafting error because the phrase ''by the carrier seeking the discontinuance''

separately to suggest that the Board ought to consider changing this regulation. AATR's appeal understandably cites an extensive list of cases in which the agency has allowed carrier-specific ''no local traffic'' certifications via the notice process, (AATR Appeal 8–9), and—in considering this overwhelming precedent—I find that the Board, to carry out the rail transportation policy (RTP) at 49 U.S.C. 10101, need not routinely subject carriers to the different, more burdensome petition process in similar future cases. Over more than 30 years, the Board has rightly saved taxpayers and many entities, including small businesses, substantial resources by cutting up to 90 days out of the exemption process and eliminating a significant number of unneeded filings and decisions. *See* 49 CFR part 1121 (procedures for petitions for exemption), 49 CFR 1152.60 (special rules for abandonment and discontinuance petitions for exemptions); 49 CFR 1152.50 (exempt abandonments and discontinuances); *see also* 49 U.S.C. 10101(2) (minimizing the need for regulatory control over the rail transportation system), section 10101(7) (reducing regulatory barriers to entry and exit), section 10101(15) (providing for expeditious handling of proceedings). Though not the highest agency priority, the Board should consider, at the appropriate time, amending its discontinuance exemption regulations to allow carrier-specific certifications and once again achieve these savings.[2]

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2023–24672 Filed 11–7–23; 8:45 am]

BILLING CODE 4915–01–P

does not appear in the related regulation or preamble. I also note that, after the agency issued the final rule and associated **Federal Register** notice, the D.C. Circuit—in upholding a remand decision that embraced both the abandonment and discontinuance exemption proceedings—stated that the ''originally proposed definition of 'out of service,' which encompassed only rail lines carrying *no traffic at all* for at least two years, had been expanded in the final rule to include lines carrying overhead traffic, *i.e.,* traffic that neither originates nor terminates on a line and can be rerouted over other lines.'' *Ill. Com. Comm'n* v. *ICC,* 848 F.2d 1246, 1249 (D.C. Cir. 1988) (emphasis added).

[2] As part of the rulemaking process, the Board should consider any necessary protections for when a carrier-specific certification would raise problems relevant to carrying out the RTP, particularly with respect to competition. But precedent shows such problems are far from the norm. The suggested future rulemaking could also address any problems or inconsistencies with the agency's treatment of atypical cases. *See e.g., Consol. R. Corp.—Exemption—Aban. of the Weirton Secondary Track in Harrison & Tuscarawas, Cntys., Ohio,* AB 176 (ICC decided June 7, 1989) (revoking a class exemption as applied to the proposed abandonment at issue and finding that a more thorough review of the transaction was necessary to carry out the national rail transportation policy).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2023–1340]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Pilots Convicted of Alcohol or Drug-Related Motor Vehicle Offenses or Subject to State Motor Vehicle Administrative Procedure

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 8, 2023. The collection involves receiving and maintaining correspondence required to be sent to the FAA from pilots who have been involved in a drug- or alcohol-related motor vehicle action. The information to be collected will be used to and/or is necessary because the FAA must identify airmen with multiple drug- or alcohol-related motor vehicle actions and verify traffic conviction information in order to support the FAA's Aviation Safety, Office of Aerospace Medicine, Aerospace Medical Certification Division, for their requirements to evaluate the qualifications of that airman to hold a medical certificate.

DATES: Written comments should be submitted by December 8, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Christopher Marks by email at: *Christopher.Marks@faa.gov;* phone: 405–954–2789.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0543.

Title: Pilots Convicted of Alcohol or Drug-Related Motor Vehicle Offenses or Subject to State Motor Vehicle Administrative Procedure.

Form Numbers: FAA Form 1600–85 has been created since the 60 day FRN has been published.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 8, 2023 (88 FR 37596). After a study and audit conducted from the late 1970's through the 1980's by the Department of Transportation, Office of the Inspector General, (DOT/OIG), the DOT/OIG recommended the FAA find a way to track alcohol abusers and those dependent on the substance that may pose a threat to the National Airspace (NAS). Through a Congressional act issued in November of 1990, the FAA established a Driving Under the Influence (DUI) and Driving While Intoxicated (DWI) Investigations Branch. The final rule for this program is found in Title 14 Code of Federal Regulations (CFR)—Part 61 § 61.15.

This regulation calls for pilots certificated by the FAA to send information regarding Driving Under the Influence (or similar charges) of alcohol and/or drugs to the FAA within 60 days from either an administrative action against their driver's license and/or criminal conviction. Part of the regulation also calls for the FAA to seek certificate action should an airman be involved in multiple, separate drug/alcohol related motor vehicle incidents within a three-year period. Information sent by the airmen is used to confirm or refute any violations of these regulations, as well as by the Civil Aerospace Medical Institute (CAMI) for medical qualification purposes. Collection by CAMI is covered under a separate OMB control number 2120–0034.

An airman is required to provide a written report, with the following information: name, address, date of birth, airman certificate number, the type of violation which resulted in the

conviction or administrative action, the state which holds the records or action, and a statement of whether the motor vehicle action resulted from the same incident or arose out of the same factual circumstances related to a previously reported motor vehicle action. A privacy act statement and a new FAA form number 1600–85 was created and added to the online submission portal.

Respondents: 480 FAA airmen with drug and alcohol related motor vehicle actions provide approximately 599 reports per year over the last three years.

Frequency: On occasion.

Estimated Average Burden per Response: 30 minutes.

Estimated Total Annual Burden: 30 minutes per report and 299.5 hours for all reports annually.

Issued in Oklahoma City, OK, on November 3, 2023.

Christopher Marks,

Security Specialist, Security & Hazardous Materials Safety/Enforcement Standards & Policy Division, AXE–900.

[FR Doc. 2023–24716 Filed 11–7–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2023–0029]

Biannual Request for Information on the Status of the Electric Vehicle (EV) Charger Industry

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice; request for information (RFI).

SUMMARY: On February 21, 2023, FHWA established a Build America, Buy America (BABA) implementation plan by publishing a temporary public interest waiver of Buy America requirements for steel, iron, manufactured products, and construction materials in electric vehicle (EV) chargers. This short-term, temporary waiver was structured to enable EV charger acquisition and installation to immediately proceed while also ensuring the application of Buy America to EV chargers by the phasing out of the waiver over time. While promulgating the final waiver, FHWA announced that it would conduct biannual RFIs to receive information on the status of the EV charger industry. Requests for comment include, but are not limited to, the number of chargers recently produced by EV charger manufacturers, projections on chargers expected to be produced, and the number of EV chargers recently purchased by recipients of Federal financial assistance and projected to be purchased by recipients of Federal financial assistance in the near future.

DATES: Comments must be received on or before December 26, 2023. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit comments by only one of the following ways:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.
- *Instructions:* You must include the agency name and docket number at the beginning of your comments. Except as described below under the heading ''Confidential Business Information,'' all submissions received, including any personal information provided, will be posted without change or alteration to *www.regulations.gov.* For more information, you may review the U.S. DOT's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477).

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Brian Hogge, FHWA Office of Infrastructure, (202) 366–1562, or via email at *Brian.Hogge@dot.gov*. For legal questions, please contact Mr. David Serody, FHWA Office of the Chief Counsel, (202) 366–4241, or via email at *David.Serody@dot.gov.* Office hours for FHWA are from 8 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

A copy of this notice, all comments received on this notice, and all background material may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic retrieval assistance and guidelines are also available at *www.regulations.gov.* An electronic copy of this document also may be downloaded from the Office of the Federal Register's website at: *www.FederalRegister.gov* and the U.S. Government Publishing Office's website at: *www.GovInfo.gov.*

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 notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI.

You may ask FHWA to give confidential treatment to information you give to the Agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send FHWA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. The FHWA will protect confidential information complying with these requirements to the extent required under applicable law. If DOT receives a FOIA request for the information that the applicant has marked in accordance with this notice, DOT will follow the procedures described in its FOIA regulations at 49 CFR 7.29. Only information that is marked in accordance with this notice and ultimately determined to be exempt from disclosure under FOIA and § 7.29 will not be released to a requester or placed in the public docket of this notice. Submissions containing CBI should be sent to: Mr. Brian Hogge, FHWA, 1200 New Jersey Avenue SE, HICP–20, Washington, DC 20590 via mail or via email at *brian.hogge@dot.gov.* Any comment submissions that FHWA receives that are not specifically designated as CBI will be placed in the public docket for this matter.

Background

On August 31, 2022, FHWA issued a notice of a proposed waiver of Buy America requirements for EV chargers, at 87 FR 53539 (''Proposed Waiver''). After reviewing the comments received, on February 21, 2023, FHWA established a BABA Implementation Plan for EV charging equipment through a temporary public interest waiver of Buy America requirements for steel, iron, manufactured products, and construction materials in EV chargers under 23 U.S.C. 313 and section 70914

of the Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act (IIJA) (Pub. L. 117–58), at 88 FR 10619 (''Final Waiver''). As of March 23, 2023 (the effective date), the Final Waiver applied to all EV chargers manufactured before July 1, 2024, whose final assembly occurs in the United States, and whose installation has begun by October 1, 2024 (''the Final Assembly Phase''). Starting with EV chargers manufactured on or after July 1, 2024, FHWA will begin to phase out coverage of EV chargers under the Final Waiver, and the Final Waiver will then only apply to EV chargers manufactured on or after July 1, 2024, whose final assembly occurs in the United States, and for which the cost of components manufactured in the United States is at least 55 percent of the cost of all components (''the 55 percent phase''). Further, under the Final Waiver, if an EV charger's housing is predominantly iron or steel, such housing is not covered by the Final Waiver at any time; instead, such housing must comply with FHWA's existing Buy America requirements.

The FHWA intends to issue at least one additional RFI before July 1, 2024.

Comments Received After Issuance of Waiver

In accordance with the provisions of section 117 of the SAFETEA–LU Technical Corrections Act of 2008 (Pub. L. 110–244), upon publishing the Final Waiver in the **Federal Register**, FHWA provided an opportunity for public comment on this finding until March 22, 2023.[1] The FHWA received four comments during this period: one from the Information Technology Industry Council (ITI), one from an individual from the Vogel Group (Vogel), one from the Nucor Corporation (Nucor), and one from the Aluminum Extruders Council and Aluminum Extrusions Fair Trade Committee (AEC/AEFTC). As FHWA believes that communication and collaboration with stakeholders is key to ensuring that the Final Waiver both enables EV charger acquisition and installation to immediately proceed while also ensuring the application of Buy America to EV chargers, it is taking this opportunity to respond to these comments.

The ITI commented that it supported the Final Waiver and urged the U.S. Government as a whole to consider waiving the application of BABA procurement preferences for information technology procured as part of infrastructure projects. The FHWA appreciates ITI's support but issuing a governmentwide waiver is beyond the scope of this comment period and FHWA's authority.

Vogel commented that there is growing concern that there is not enough domestic capacity to meet the demand for the production of the housing of EV chargers in the United States and asked how FHWA plans to monitor the cost and availability of EV chargers if Buy America-compliant housing is not available. The FHWA would welcome data on this issue (see the questions for EV charger manufacturers below) and will use these biannual RFIs to monitor the cost and availability of EV chargers. Finally, Vogel questioned whether FHWA is prepared to act if a State applies for a waiver of Buy America requirements for the housing of an EV charger. The FHWA will respond to all waiver requests with respect to the housing of an EV charger in accordance with FHWA's existing policies and applicable laws and regulations.

Vogel also asked several questions regarding the Final Waiver's applicability to the housing of EV chargers. In particular, Vogel questioned whether it is acceptable to manufacture housing components in the United States, export the housing components for partial assembly overseas, and then have the partially-completed charger imported for final assembly in the United States; what FHWA considers to be sufficient documentation that the housing components were produced in the United States before exportation; and what FHWA considers to be the steel or iron content that makes an EV charger's housing predominantly iron or steel. To the extent that FHWA has not addressed these concerns in existing guidance documents discussing FHWA's Buy America requirements, including the set of frequently asked questions (FAQs) responding to questions concerning the Final Waiver,[2] FHWA will seek to do so in subsequent guidance documents. In this RFI, FHWA also invites comments on these FAQs as it works to develop additional guidance that is useful for stakeholders to achieve the Final Waiver's goals of enabling EV charger acquisition and installation to quickly proceed while ensuring the application of Buy America to EV chargers.

Nucor and the AEC/AEFTC both provided similar comments, which largely repeated concerns raised in their separate comments on the Proposed Waiver. Both commenters repeated that the Final Waiver is contrary to Congressional intent in enacting BIL, where Congress found, in section 70911(4), that ''entities using taxpayer-financed Federal assistance should give a commonsense procurement preference for the materials and products produced by companies and workers in the United States.'' Nucor further added that the Final Waiver is contrary to Congressional intent in enacting section 165 of the Surface Transportation Assistance Act of 1982 (Pub. L. 97–424), which expanded Buy America coverage to steel products. The AEC/AEFTC commented that the Final Waiver is generally contrary to the Administration's policy of maximizing the use of American products in federally funded infrastructure and promoting domestic manufacturing in clean energy. Nucor and AEC/AEFTC also reiterated their concerns, stated in their comments to the Proposed Waiver, regarding the perceived unlimited duration of the Final Waiver, as both commenters stated that there is no end date specifically provided in the Final Waiver.

Nucor also repeated the claim it made in the Proposed Waiver that the Final Waiver is contrary to the Administration's policy of promoting clean energy because it allows for the use of imported steel, which prioritizes environmentally unfriendly foreign steel at the expense of cleaner America-made steel. Nucor further repeated that FHWA has successfully applied its Buy America requirements to steel components and subcomponents of manufactured products for decades, that suppliers of FHWA products have needed to comply with these requirements for years, and that there is nothing unique about steel used in EV chargers that would make compliance more difficult. Finally, Nucor repeated its belief that domestic steel for use in EV chargers is readily available.

As these comments from Nucor and the AEC/AEFTC repeat what these commenters provided in response to the Proposed Waiver, which FHWA responded to in issuing the Final Waiver, FHWA does not find it necessary to provide further detailed responses.[3]

[1] Pursuant to section 117(a)(2) of the SAFETEA–LU Technical Corrections Act of 2008, FHWA did not delay the effective date of its finding due to the requirement that it provide an opportunity for public comment.

[2] The FAQs related to the Final Waver are available at: *https://www.fhwa.dot.gov/construction/contracts/buyam_qaev/buyam_qaev.pdf.* The FHWA has also issued other FAQs regarding Buy America, which can be found at: *https://www.fhwa.dot.gov/construction/contracts/buyam_qa.cfm.*

[3] For FHWA's response that the waiver is contrary to Congressional intent in enacting section 165 of

Continued

The AEC/AEFTC emphasized that it strongly opposes the Final Waiver's coverage of aluminum extrusions used in EV chargers. The AEC/AEFTC opined that aluminum extrusions—used in EV chargers and components of EV chargers—are readily available from domestic sources. While this may be true, removing aluminum extrusions from coverage under this waiver would mean that these extrusions would need to comply with existing Buy America requirements under 23 U.S.C. 313 and section 70914 of BIL, and it is not clear to FHWA whether the domestic supply of aluminum extrusions mentioned by AEC/AEFTC comply with these requirements. The comment did not provide data on whether all manufacturing processes used to make aluminum extrusions occurred in the United States, nor did it state the amount of extrusions that are produced in compliance with Buy America requirements and the amount required by the EV charger industry for FHWA to ensure that removing coverage of extrusions from the Final Waiver would not detrimentally impact the delivery of EV infrastructure projects.

Request for Information

In the Final Waiver, FHWA announced that it would conduct biannual RFIs during the final assembly phase to assess industry progress on producing an EV charger that would conform with the 55 percent phase and determine whether the EV charger industry is on track to meet the timeline set out in the Final Waiver. As stated in the Final Waiver, based on the information received in response to these RFIs, FHWA may modify the start date of the 55 percent phase after providing adequate notice of its intention to do so. Under the 55 percent phase, as laid out in the Final Waiver, EV chargers that are manufactured on and after July 1, 2024, would conform with the Final Waiver only if final assembly occurs in the United States and the cost of components manufactured in the United States exceeds 55 percent of the cost of all components.

The FHWA encourages commenters to share all information responsive to the questions below, including confidential information. Doing so will allow FHWA a complete picture of the current state of the domestic EV charger industry and its anticipated ability to meet 55 percent domestic content standard by July 1, 2024, as provided in the final waiver. The FHWA therefore encourages detailed responses where possible, including confidential information where applicable, from all stakeholders to ensure that FHWA has a complete picture of the domestic EV charging industry.

The FHWA requests information on the following questions. Please indicate in your written response which question(s) you are answering. The FHWA encourages stakeholders to answer as many questions as possible.

EV Charger Manufacturers

1. Approximately how many EV chargers have you manufactured since the beginning of calendar year 2023 until now that are ready for installation? What are the charger types (*i.e.,* direct-current fast chargers (DCFC) or alternating-current level 2 (ACL2) chargers) and specifications (*e.g.,* maximum charging power, connector type)?

a. Of the chargers manufactured since the beginning of calendar year 2023 until now that are ready for installation, how many have final assembly occur in the United States and have the housing, if predominantly iron or steel, comply with FHWA's existing Buy America requirements? What are the types of these chargers (*i.e.,* DCFC or ACL2 chargers) and specifications (*e.g.,* maximum charging power, connector type)?

b. Of the chargers manufactured since the beginning of the calendar year until now that are ready for installation, how many have final assembly occur in the United States; have the housing, if predominantly iron or steel, comply with FHWA's existing Buy America requirements; *and* have the cost of components manufactured in the United States be at least 55 percent of the cost of all components? What are the types of these chargers (*i.e.,* DCFC or ACL2 chargers) and specifications (*e.g.,* maximum charging power, connector type)?

2. Of the EV chargers you have manufactured since the beginning of calendar year 2023 until now that are ready for installation, how many are intended to be compliant with FHWA's NEVI Standards and Requirements (23 CFR part 680)?

a. Of these NEVI-compliant chargers referred to in question 2, how many have final assembly occur in the United States and have housing, if predominantly iron or steel, that complies with FHWA's existing Buy America requirements? What are the charger types (*i.e.,* DCFC or ACL2 chargers) and specifications (*e.g.,* maximum charging power, connector type)?

b. Of these NEVI-compliant chargers referred to in question 2, how many have final assembly occur in the United States; have housing, if predominantly iron or steel, that complies with FHWA's existing Buy America requirements; *and* have the cost of components manufactured in the United States be at least 55 percent of the cost of all components? What are the charger types (*i.e.,* DCFC or ACL2 chargers) and specifications (*e.g.,* maximum charging power, connector type)?

3. What is the average time between when a charger is ordered and when it is finished being manufactured? What is the average time between when a charger is ordered and when it is shipped? Do these times vary? If so, why?

4. Approximately how many EV chargers do you expect to produce from now until June 30, 2024? What do you expect the charger types (*i.e.,* DCFC or ACL2 chargers) and specifications (*e.g.,* maximum charging power, connector type) to be?

5. Of the chargers expected to be produced from now until June 30, 2024, how many are expected to be compliant with FHWA's NEVI Standards and Requirements (23 CFR part 680)?

a. Of the NEVI-compliant chargers expected to be produced from now until June 30, 2024, how many are expected to have final assembly occur in the United States and have housing, if predominantly iron or steel, that complies with FHWA's existing Buy America requirements? What are the expected charger types (*i.e.,* DCFC or ACL2 chargers) and specifications (*e.g.,* maximum charging power, connector type)?

b. Of the NEVI-compliant chargers expected to be produced from now until June 30, 2024, how many are expected to have final assembly occur in the United States; have housing, if predominantly iron or steel, that complies with FHWA's existing Buy

---

the Surface Transportation Assistance Act of 1982 and BIL and Administrative policy regarding domestic production, see *id.* At 10623. For FHWA's response to Nucor's comment regarding the perceived unlimited duration of the waiver, see *id.* At 10622–23. For FHWA's response to Nucor's claims on the environmental impacts of foreign steel, see 88 FR at 10624. For FHWA's response to Nucor's comment that FHWA has successfully applied its Buy America requirements to steel components of manufactured products for decades, see *id.* At 10624. For FHWA's response that there is nothing unique about steel used in EV chargers that would make compliance more difficult, see *id.* For FHWA's response to Nucor's comment that domestic steel for use in EV chargers is readily available, see *id.* At 10632–33. The FHWA notes that in response to comments by Nucor and others that the domestic steel industry has the capacity to supply steel for use in EV chargers, FHWA determined that it was not in the public interest to apply the waiver to the housing of an EV charger if it is predominantly iron or steel.

America requirements; *and* have the cost of components manufactured in the United States be at least 55 percent of the cost of all components? What are the expected charger types (*i.e.,* DCFC or ACL2 chargers) and specifications (*e.g.,* maximum charging power, connector type)?

6. For chargers expected to be ordered from now until June 30, 2024, what is the average expected time between when a charger is ordered and when its manufacture is complete? What is the average expected time between when a charger is ordered and when it is shipped? Do you expect that these times will vary? If so, why?

7. How have Federal incentives for EVs and EV charging infrastructure (such as the EV tax credits included in the Inflation Reduction Act (Pub. L. 117–169) and the Federal funding for EV charging infrastructure included in BIL) affected your business plans and models? To what extent have they supported or inhibited expansion or onshoring of your operations?

8. Will you be able to supply EV chargers to all 50 States, as well as the District of Columbia and Puerto Rico? Have you experienced or do you expect to experience any limitations to distributing EV chargers to certain locations? If so, what are these limitations?

9. What obstacles, if any, have you encountered in conducting final assembly of EV chargers in the United States? What obstacles do you expect to face in the future?

10. What costs have you incurred in manufacturing EV chargers that comply with the Final Waiver? What costs do you expect to incur?

11. What obstacles, if any, have you encountered in manufacturing EV chargers where the cost of components manufactured in the United States is at least 55 percent of the cost of all components? What obstacles do you expect to face in the future?

12. What obstacles, if any, have you encountered in manufacturing EV chargers where the housing, if predominantly iron or steel, complies with FHWA's existing Buy America requirements?

13. What benefits have you achieved by producing EV chargers in the United States compared to abroad (*e.g.,* jobs created, wages paid, innovations spurred, more reliable supply chains, lower transportation costs)?

14. Are there any components currently manufactured outside of the United States that could be manufactured in the United States at reasonable cost but are not? If yes, what are those components, and why do you believe that they are not being manufactured in the United States?

15. What steps can be taken to increase the number of EV chargers that have final assembly occur in the United States; have the cost of components manufactured in the United States be at least 55 percent of the cost of all components; and, if the housing is predominantly iron or steel, have housing that complies with FHWA's existing Buy America requirements? How long might it take to undertake those steps?

16. What is the volume of EV chargers that could be shifted to being manufactured to the specifications stated in question 15? How long would that shift take? How many EV chargers could be manufactured if that shift occurred and over what time period?

For Recipients of Federal Financial Assistance

17. Please identify all EV charger manufacturers currently selling, manufacturing, or operating EV chargers in the United States, of which you are aware.

18. Which EV charger manufacturers are you aware of that produce an EV charger where final assembly occurs in the United States and where, if the housing is predominantly iron or steel, the housing complies with BABA's iron and steel standards? Which EV manufacturers are you aware of that produce an EV charger where final assembly occurs in the United States; where the cost of components manufactured in the United States is at least 55 percent of the cost of all components; *and* where, if the housing is predominantly iron or steel, the housing complies with FHWA's existing Buy America requirements?

19. What sources of Federal financial assistance have you used to purchase EV chargers from the beginning of calendar year 2023 until now? For each source, please list the specific source of Federal financial assistance (*e.g.,* FHWA NEVI funds, EPA Clean School Bus Program funds), include the number of EV chargers purchased using that source of funds, the charger types purchased (*i.e.,* DCFC or ACL2 chargers) and their specifications (*e.g.,* maximum charging power, connector type)?

20. How many EV chargers do you expect to purchase from now until June 30, 2024, using Federal financial assistance? Please list all sources of Federal funding used (*e.g.,* FHWA NEVI funds, EPA Clean School Bus Program funds). For each source, please include the number of EV chargers purchased using that source of funds, the charger types purchased (*i.e.,* DCFC or ACL2 chargers) and their specifications (*e.g.,* maximum charging power, connector type)?

21. What is the average time between when EV chargers are purchased and when they are delivered? What is the average time between when EV chargers are purchased and when they are installed and operational? Have you found these times to vary? If so, why do you believe this is the case?

22. Have you received different cost estimates for EV chargers manufactured before and after the publication of the Final Waiver on February 21, 2023? If so, what is the difference?

23. Have you received different delivery time estimates for EV chargers manufactured before and after the publication of the Final Waiver on February 21, 2023? If so, what is the difference?

24. Has any difficulty in procuring chargers that are compliant with the Final Waiver caused you to slow your implementation of EV charging? If so, how many chargers were affected and how long was the delay?

General

25. The FHWA also requests comments on the FAQs on Buy America requirements for EV chargers that are posted at *https://www.fhwa.dot.gov/construction/contracts/buyam_qaev/buyam_qaev.pdf,* as well as any additional issues or topics that you believe would be useful for FHWA to address in subsequent guidance. In providing such comments, please refer to the specific question number in the FAQs that you are commenting on.

Issued in Washington, DC, under authority delegated in 49 CFR 1.85.

Shailen P. Bhatt,

Administrator, Federal Highway Administration.

[FR Doc. 2023–24696 Filed 11–7–23; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2015–0036]

Petition for Extension of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on October 13, 2023, Union Pacific Railroad Company (UPRR) petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 232 (Brake

System Safety Standards for Freight and Other Non-Passenger Trains and Equipment; End-of-Train Devices). The relevant Docket Number is FRA–2015–0036.

Specifically, UPRR requests to continue operating extended haul trains for distances of up to 1,680 miles, beyond the limit of 1,500 miles stated in 49 CFR 232.213, *Extended haul trains.* In support of its request, UPRR states that it reviews with FRA ''the list of trains associated with this waiver at a frequency of no less than once per quarter'' and ''adjustments are made accordingly.'' UPRR further explains that ''over a 56-month period, the incident rate has been no more than .055%[, which were] four events comprised of wheelset, axle, and journal bearing defects.'' UPRR also notes that for the eight-year history of this waiver, UPRR ''has not identified any adverse effect on the safety of operations'' and that the waiver extension would ''continue to support personnel safety, reduce critical resource idle time, and have a positive impact on the environment.''

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov.*

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Communications received by January 8, 2024 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), the U.S. Department of Transportation (DOT) solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2023–24643 Filed 11–7–23; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request Relating to Affordable Care Act Notice of Rescissions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning affordable care act notice of rescissions.

DATES: Written comments should be received on or before January 8, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include OMB control number 1545–2180 or Affordable Care Act Notice of Rescissions.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Kerry Dennis at (202) 317–5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.L.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Affordable Care Act Notice of Rescissions.

OMB Number: 1545–2180.

Regulation Project Numbers: TD 9744.

Abstract: This document contains final regulations regarding grandfathered health plans, preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, coverage of dependent children to age 26, internal claims and appeal and external review processes, and patient protections under the Affordable Care Act.

Current Actions: There are no changes to the regulation or burden.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,533.

Estimated Total Annual Burden Hours: 20 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. 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.

Approved: November 1, 2023.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2023–24656 Filed 11–7–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs (VA), Veterans Health Administration (VHA).

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, ''Veteran Child Care Programs—VA'' (169VA10NC). This system is used to assist VA in assessing whether it should and can feasibly assist qualified Veterans who need childcare to receive health care services.

DATES: Comments on this amended 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 the 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 ''Veteran Child Care Programs—VA'' (169VA10NC). Comments received will be available at regulations.gov for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Stephania Griffin, VHA Chief Privacy Officer, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; telephone (704) 245–2492 (Note: this is not a toll-free number).

SUPPLEMENTARY INFORMATION: VA is amending the system of records by revising the System Number, System Location, System Manager, Purpose, Categories of Records, Records Source Categories, Routine Uses of Records Maintained in the System, Policies and Practices for Retention and Disposal of Records, and Policies and Practices for Retrieval of Records. VA is republishing the system notice in its entirety.

The System Number is being updated from 169VA10NC to 169VA10 to reflect the current VHA organizational routing symbol. The System Location is being updated to include information on where to find address locations for VA facilities.

The Purpose is being updated to reflect that the records are used to provide appropriate childcare services to children in the program and to clarify that research includes quality improvement activities. The Purpose is also being updated to remove reference to ordering and delivery of equipment.

The System Manager is being updated to replace ADUSH for Clinical Operations, with Deputy Assistant Under Secretary for Health for Operations.

The Categories of Records in the System is being updated to delete reference to the collection of Social Security Numbers as this information is not being captured.

The Records Source Categories is being updated to include parent/guardian. Routine use number 13 is being added to state, ''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 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 or persons is reasonably necessary to assist in connection with VA efforts to respond to the suspected or confirmed breach or to prevent, minimize or remedy such harm.''

Policies and Practices for Retrieval of Records is being updated to remove the Social Security Number.

Policies and Practices for Retention and Disposal of Records is being updated to include VA Records Control Schedule (RCS) 10–1, Item Numbers 3075.1 and 3075.12.

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 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), 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 September 28, 2023 for publication.

Dated: November 3, 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:

''Veteran Child Care Programs—VA'' (169VA10).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are located at each Department of Veterans Affairs (VA) health care facility where the childcare program is in place (in most cases, backup information is stored at off-site locations). Address locations for VA facilities are listed in Appendix 1 of the biennial publication of the VA Privacy Act Issuances. Subsidiary record information is maintained by individuals, organizations and/or agencies with whom VA has a contract or agreement to perform such services, as VA may deem practicable.

SYSTEM MANAGER(S):

Official responsible for policies and procedures: Deputy Assistant Under Secretary for Health for Operations, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Telephone 202–461–7064 (this is not a toll-free number).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

38 U.S.C. 501.

PURPOSE(S) OF THE SYSTEM:

These records are used to provide appropriate childcare services to the children in the program; for statistical analysis to produce various management, workload tracking, and follow-up reports; for determining entitlement and eligibility for VA benefits; for quality assurance audits and reviews; to track and evaluate services for the planning, distribution and utilization of resources; and personnel management and evaluation. The data may be used for VA's extensive research programs, including quality improvement activities, in accordance with VA policy.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

These records include information on children who receive childcare and the children's parents and/or guardians who are receiving treatment at VA.

CATEGORIES OF RECORDS IN THE SYSTEM:

The category of records in the system include: (1) Identifying information for child (*e.g.,* name, birth date, age, telephone number); (2) child's primary care physician name and contact information; and (3) emergency contact information for parent/guardian (*e.g.,* name of parent/guardian, address, relationship, telephone number, alternate contact person).

RECORD SOURCE CATEGORIES:

Information in this system of records may be provided by the Veteran, parent/guardian of the child or family members.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. *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 a violation or potential violation of law, whether civil, criminal or regulatory in nature, 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 such a violation or potential violation. 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.

2. *Disease Tracking, Patient Outcomes, Other Health Information Required for Program Accountability:* To another Federal agency or the District of Columbia's government in response to its request or at the initiation of VA, in connection with disease tracking, patient outcomes or other health information required for program accountability.

3. *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 parent/guardian of the child who is the subject of the record.

4. *National Archives and Records Administration (NARA):* To the 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.

5. *Department of Justice (DoJ), Litigation, Administrative Proceeding:* To the 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. *Equal Employment Opportunity Commission (EEOC):* To the 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.

7. *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.

8. *Federal Agencies, Fraud and Abuse:* To other Federal agencies to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

9. *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.

10. *Family, Partner, for Notification of a Child's Status:* To the extent necessary, on a need-to-know basis, and consistent with good ethical practices, to family members or persons with whom the child has a meaningful relationship.

11. *Federal Labor Relations Authority (FLRA):* To the 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.

12. *Merit Systems Protection Board (MSPB):* To the 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 otherwise authorized by law.

13. *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 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 or persons is reasonably necessary to assist in connection with VA efforts to respond to the suspected or confirmed breach or to prevent, minimize or remedy such harm.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are currently maintained on paper, microfilm, electronic media including images and scanned documents, or laser optical media in the consolidated health record at the health care facility where care was rendered.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name or other assigned identifiers of the Veteran receiving VA services associated with the childcare episode.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records in this system are retained and disposed of in accordance with the schedule approved by the Archivist, VA Records Control Schedule (RCS) 10–1, Item Numbers 3075.1 and 3075.12.

ADMINISTRATIVE, TECHNICAL AND PHYSICAL SAFEGUARDS:

1. Access to and use of national administrative databases, warehouses and data marts are limited to those

persons whose official duties require such access, and VA has established security procedures to ensure that access is appropriately limited. Information security officers and system data stewards review and authorize data access requests. VA regulates data access with security software that authenticates users and requires individually unique codes and passwords. VA provides information security training to all staff and instructs staff on the responsibility each person has for safeguarding data confidentiality.

2. Physical access to computer rooms housing national administrative databases, warehouses and data marts is restricted to authorized staff and protected by a variety of security devices. Unauthorized employees, contractors and other staff are not allowed in computer rooms. The Federal Protective Service or other security personnel provide physical security for the buildings housing computer rooms and data centers.

3. Data transmissions between operational systems and national administrative databases, warehouses and data marts maintained by this system of record are protected by state-of-the-art telecommunication software and hardware. This may include firewalls, intrusion detection devices, encryption and other security measures necessary to safeguard data as it travels across the VA Wide Area Network.

4. In most cases, copies of back-up computer files are maintained at off-site locations.

5. VA maintains Business Associate Agreements and Non-Disclosure Agreements where appropriate with contracted resources in order to maintain confidentiality of the information.

RECORD ACCESS PROCEDURE:

Individuals seeking information on the existence and content of records in this system pertaining to where the child participated in the childcare program should contact the system manager in writing as indicated above. A request for access to records must contain the Veteran or primary caretaker'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 or their children 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 PROCEDURE:

Generalized notice is provided by the publication of this notice. For specific notice, see Record Access Procedure, above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

77 FR 56914 (September 14, 2012).

[FR Doc. 2023–24681 Filed 11–7–23; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 88 Wednesday,
No. 215 November 8, 2023

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 Part 419

Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 419

[CMS–1793–F]

RIN 0938–AV18

Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule describes the agency's actions on remand from the United States (U.S.) District Court for the District of Columbia to craft a remedy in light of the U.S. Supreme Court's decision in *American Hospital Association* v. *Becerra,* 142 S. Ct. 1896 (2022), relating to the adjustment of Medicare payment rates for drugs acquired under the 340B Program from calendar year (CY) 2018 through September 27th of CY 2022.

DATES: This rule is effective January 8, 2024.

FOR FURTHER INFORMATION CONTACT: Cory Duke, *Cory.Duke@cms.hhs.gov,* or (410) 786–0631.

SUPPLEMENTARY INFORMATION:

I. Background

A. OPPS Payment Policy for Drugs Acquired Through the 340B Program

1. Overview

Under the Hospital Outpatient Prospective Payment System (hereinafter referred to as OPPS), we generally set payment rates for separately payable drugs and biologicals (hereinafter referred to collectively as ''drugs'') under section 1833(t)(14)(A) of the Social Security Act (hereinafter referred to as ''the Act'') (42 U.S.C. 1395*l*(t)(14)(A)). Section 1833(t)(14)(A)(iii)(II) of the Act (42 U.S.C. 1395*l*(t)(14)(A)(iii)(II)) provides that, if hospital acquisition cost data are not available, the payment amount is the average price for the drug in a year established under sections 1842(o), 1847A, or 1847B of the Act (42 U.S.C. 1395u(o), 42 U.S.C. 1395w–3a, & 42 U.S.C. 1395w–3b), as the case may be. Payment rates for drugs are usually established under section 1847A of the Act (42 U.S.C. 1395w–3a), which generally sets a default rate of the average sales price (ASP) plus 6 percent. Section 1833(t)(14)(A)(iii)(II) of the Act (42 U.S.C. 1395*l*(t)(14)(A)(iii)(II)) also provides that the average price for the drug in the year as established under section 1847A of the Act (42 U.S.C. 1395w–3a), is calculated and adjusted by the Secretary of the Department of Health and Human Services (Secretary) as necessary for purposes of paragraph (14).

In the calendar year (CY) 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), the Centers for Medicare & Medicaid Services (CMS) reexamined the appropriateness of paying the ASP plus 6 percent for drugs acquired through the 340B Drug Pricing Program (hereinafter referred to as the ''340B Program''), a Health Resources and Services Administration (HRSA)-administered program that allows covered entities to purchase certain covered outpatient drugs at discounted prices from drug manufacturers. Based on findings of the Government Accountability Office (GAO),[1] the HHS Office of the Inspector General (OIG),[2] and the Medicare Payment Advisory Commission (MedPAC) [3] that 340B hospitals were acquiring drugs at a significant discount under the 340B Program, CMS adopted a policy beginning in 2018 generally to pay an adjusted amount of ASP minus 22.5 percent for certain separately payable drugs or biologicals acquired through the 340B Program. This adjustment amount was based on our concurrence with an analysis by MedPAC that concluded that the estimated average minimum discount of 22.5 percent of ASP adequately represented the average minimum discount that a 340B participating hospital received for separately payable drugs under the OPPS (82 FR 59354 through 59371). Our intent in implementing this payment reduction was to reflect more accurately the actual costs incurred by participating hospitals in acquiring 340B drugs. We stated our belief that such changes would allow Medicare beneficiaries and the Medicare program to pay a more appropriate amount when hospitals participating in the 340B Program furnished drugs to Medicare beneficiaries that were purchased under the 340B Program (82 FR 59353 through 59371).

2. OPPS Payment for 340B Drugs in CY 2018 Through September 27th of 2022

From January 1, 2018, through September 27, 2022, under the OPPS we generally paid for certain separately payable drugs acquired through the 340B Program at ASP minus 22.5 percent. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from ASP plus 6 percent to ASP minus 22.5 percent. We also noted that critical access hospitals are not paid under the OPPS, and therefore were not subject to the OPPS 340B drug payment adjustment policy (hereinafter referred to as the ''340B Payment Policy''). We also exempted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment primarily due to these hospitals receiving special payment adjustments under the OPPS. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change did not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

Additionally, as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, we implemented modifiers ''JG'' and ''TB'' effective January 1, 2018. Hospitals paid under the OPPS, other than types of hospitals excluded from the OPPS (such as critical access hospitals) or exempted from the 340B Payment Policy for CY 2018, were required to report modifier ''JG'' on the same claim line as the drug Healthcare Common Procedure Coding System (HCPCS) code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals were exempted from the 340B payment adjustment. These hospitals were required to report informational modifier ''TB'' for 340B-acquired drugs, and continued to be paid the full applicable amount, generally ASP plus 6 percent.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we

[1] Government Accountability Office. ''Medicare Part B Drugs: ''Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.'' June 2015. Available at *https://www.gao.gov/assets/gao-15-442.pdf.*

[2] Office of Inspector General. ''Part B Payment for 340B Purchased Drugs. OEI–12–14–00030''. November 2015. Available at: *https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf.*

[3] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/.*

continued the Medicare 340B payment policies that were implemented in CY 2018 and adopted a policy to pay for non-pass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than the reference biological product's ASP. Additionally, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs furnished in non-exempted off-campus provider-based departments (PBDs) paid under the Physician Fee Schedule (PFS). We adopted this payment policy for CY 2019 and subsequent years. Also, during the CY 2019 OPPS/ASC rulemaking cycle, we clarified that the 340B payment adjustment applied to drugs priced using either wholesale acquisition cost (WAC) or average wholesale price (AWP), and since the policy was first adopted, we applied the 340B payment adjustment to 340B-acquired drugs priced using these pricing methodologies. The 340B payment adjustment for WAC-priced drugs was WAC minus 22.5 percent. 340B-acquired drugs that were priced using AWP were paid an adjusted amount of 69.46 percent of AWP (83 FR 37125).[4]

For more detailed descriptions of our OPPS payment policy for drugs acquired under the 340B Program during this timeframe, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321 through 61327); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649); and the CY 2023 OPPS/ASC final rule with comment period (87 FR 71972 through 71973).

3. Payment for Non-Drug Items and Services in CY 2018 Through CY 2022

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59216, 59258), to comply with the statutory budget neutrality requirements under sections 1833(t)(9)(B) and (t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(9)(B) and (t)(14)(H)), we finalized our proposal to redistribute our estimated reduction in payments for separately payable drugs as a result of the 340B Payment Policy by increasing the conversion factor used to determine the payment amounts for non-drug items and services. As further described in the CY 2018 OPPS/ASC final rule with comment period, we used updated CY 2016 claims data and a list of 340B-eligible providers to calculate an estimated impact of $1.6 billion based on the final CY 2018 policy to pay for OPPS 340B-acquired drugs at a payment rate of generally ASP minus 22.5 percent. In order to effectuate the budget neutrality provisions of the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of the final 340B payment methodology was redistributed in an equal offsetting amount to all hospitals paid under the OPPS by increasing the payment rates by 3.19 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018. This same conversion factor adjustment applied for CYs 2019 through 2022, increasing payments for non-drug items and services in these CYs as a result of the 340B Payment Policy.

For ease of reference, we refer to the adjustments we made to payment rates for 340B-acquired drugs and the corresponding rate adjustment for non-drug services and items as the 340B Payment Policy.

B. Litigation History of the 340B Payment Policy

The 340B Payment Policy has been the subject of extensive litigation. See the 340B Remedy proposed rule for a more comprehensive summary of the litigation history (88 FR 44079 through 44080).

On June 15, 2022, the Supreme Court held that because CMS had not conducted a survey of hospitals' acquisition costs, it could not vary the payment rates for outpatient prescription drugs by hospital group. *See Am. Hosp. Ass'n* v. *Becerra,* 142 S. Ct. 1896, 1906 (2022).

The Supreme Court declined to opine on the appropriate remedy, *id.* at 1903, and remanded the case to the U.S. Court of Appeals for the D.C. Circuit, *id.* at 1906, which in turn remanded it to the U.S. District Court for the District of Columbia, *see Am. Hosp. Ass'n* v. *Becerra,* No. 19–5048, 2022 WL 3061709, at *1 (D.C. Cir. Aug. 3, 2022).[5] On remand to the district court, the plaintiffs filed motions seeking orders (1) vacating the portion of the CY 2022 final OPPS rule that set the reimbursement rate for 340B drugs at ASP minus 22.5 percent, which was still in effect for the remainder of 2022, and (2) requiring CMS to remedy the reduced payment amounts to 340B hospitals under the final OPPS rules for CY 2018 through CY 2022 by reimbursing them the difference between what they were paid and ASP plus 6 percent. *See Am. Hosp. Ass'n* v. *Becerra,* 1:18–cv–02084–RC, Dkts.67, 69 (D.D.C. Aug. 3, 2022).[6] On September 28, 2022, the district court ruled on the first motion, vacating the reimbursement rate for 340B-acquired drugs for the remainder of 2022. *See Am. Hosp. Ass'n* v. *Becerra,* 1:18–cv–2084–RC, 2022 WL 4534617, at *5.[7]

On January 10, 2023, the district court ruled on the second motion, issuing a remand without vacatur to give the agency the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final OPPS rules for CY 2018 through CY 2022. *See Am. Hospital Ass'n* v. *Becerra,* 1:18–cv–2084–RC, 2023 WL 143337, at *6.[8] Both courts and the Departmental Appeals Board have stayed pending challenges to payments made under the 340B Payment Policy. *See, for example, Vanderbilt Univ. Med. Ctr.* v. *Azar,* 1:20–cv–01582 (D.D.C. May 23, 2023).[9]

C. Payment for 340B-Acquired Drug Claims for September 28, 2022, Through December 31, 2022, and for CY 2023

The agency complied with the District Court's September 28, 2022, decision by uploading revised OPPS drug files to pay the default rate (generally ASP plus 6 percent) for all CY 2022 claims for 340B-acquired drugs paid from September 28, 2022, through the end of CY 2022.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71970), we finalized a policy reversing the 340B Payment Policy. To do so, we first provided that drugs acquired through the 340B Program would be paid at the default rate (generally ASP plus 6 percent) for CY 2023. Second, to ensure budget neutrality for CY 2023 OPPS payment rates as required by statute, we finalized a reduction of 3.09 percent to the 2023 OPPS conversion factor. This 3.09 percent reduction for CY 2023 offsets the prior increase of 3.19 percent

[4] The 69.46 percent of AWP was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which was similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

[5] *https://ecf.cadc.uscourts.gov/n/beam/servlet/TransportRoom.*

[6] *https://ecf.dcd.uscourts.gov/doc1/04519382229; https://ecf.dcd.uscourts.gov/doc1/04509382365.*

[7] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-79.*

[8] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-86.*

[9] *https://ecf.dcd.uscourts.gov/cgi-bin/DktRpt.pl?145369228216471-L_1_0-1.*

that was applied to the conversion factor by the 340B Payment Policy in CY 2018. This is because a downward adjustment involves a smaller percentage reduction from a larger number to get the same dollar amount as the original upward adjustment from a smaller number. More specifically, in order to achieve the original budget neutrality adjustment for CY 2018, we had to multiply the conversion factor by 1.0319. In order to offset this prior increase for the CY 2023 rule, we had to make a downward adjustment to the conversion factor, which involved dividing 1 by 1.0319, which equals 0.9691. And 1 minus 0.9691 equals 0.0309, which is where we derived the 3.09 percent reduction to the conversion factor for CY 2023. As we explained in the CY 2023 OPPS/ASC final rule, we decreased the OPPS conversion factor to offset the increase in the OPPS conversion factor in CY 2018, which originally implemented the 340B policy in a budget neutral manner. We stated: ''This adjustment to the conversion factor is appropriate in these circumstances, including because it removes the effect of the 340B policy as originally adopted in CY 2018, which was recently invalidated by the Supreme Court as explained above, from the CY 2023 conversion factor and ensures it is equivalent to the conversion factor that would be in place if the 340B Payment Policy had never been implemented'' (87 FR 71975). Additionally, we explained that we agreed with commenters, including the American Hospital Association, that under these specific circumstances it was appropriate to decrease payments for non-drug items and services by a percentage that would offset the percentage by which they were increased by the 340B Payment Policy in CY 2018 (87 FR 71975).

For more detail on the payment rate for drugs acquired under the 340B Program for CY 2023 and the corresponding adjustment to the conversion factor to maintain budget neutrality as a result of reversing the 340B adjustment and paying for all separately payable drugs at ASP plus 6 percent (or WAC plus 3 or 6 percent or 95 percent of AWP), we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71973 through 71976).

II. Summary of and Responses to Public Comments on Remedy Payment Adjustment for 340B-Acquired Drugs From CY 2018 Through September 27th of CY 2022

A. Remedy Options Considered By CMS

In the proposed rule (88 FR 44080), we evaluated several options to determine which remedy would best achieve the objective of unwinding the unlawful 340B Payment Policy while making certain OPPS providers (hereinafter referred to as ''affected 340B covered entity hospitals'' [10]) as close to whole as is administratively feasible.

We describe the different proposed remedy options and aspects of those alternative options that we considered in the proposed rule below.

1. Make Additional Payments to Affected 340B Covered Entity Hospitals for 340B-Acquired Drugs From CY 2018 Through September 27th of CY 2022 Without an Adjustment To Maintain Budget Neutrality

In the proposed rule (88 FR 44080), we considered calculating the additional amount each affected 340B covered entity hospital would have been paid for 340B-acquired drugs from CY 2018 through September 27th of CY 2022 if not for the 340B Payment Policy, and then considered paying that amount to each hospital without applying a corresponding adjustment to the conversion factor for the increased payments for non-drug items and services that were made from CY 2018 through CY 2022 due to the 340B Payment Policy. As we described, we believe that we would have the authority to make remedy payments under sections 1833(t)(2)(E) and 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(2)(E) and (t)(14)), along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)). We noted that sections 1833(t)(2)(E) and (t)(14) of the Act (42 U.S.C. 1395*l*(t)(2)(E) and (t)(14)) require budget neutrality with respect to payment adjustments to the OPPS made under those sections and there are no exceptions with respect to remedy payments. Consequently, we stated that we believe the best reading of both of those provisions is that these remedy payments are subject to budget neutrality requirements, at least when the budget neutrality adjustment would not be *de minimis.* That was consistent with the statute's general approach of budget neutralizing OPPS payment adjustments. *See, for example,* section 1833(t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(9)(B)).

We explained that section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) straightforwardly requires adjustments made under that provision to be made ''in a budget neutral manner.'' (*Accord* 65 FR 18438 (noting (t)(2)(E)'s budget neutrality requirement).) And section 1833(t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(14)(H)), relating to drug APC payment rates, states that ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but *shall be taken into account for subsequent years.*'' (Emphasis added.) In addition, section 1833(t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(9)(B)), referenced in section 1833(t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(14)(H)), states in relevant part [i]f the Secretary makes adjustments under subparagraph (A),[11] then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made.

We explained that these statutes require us to account for budget neutrality in these remedy payments. To the extent these remedy payments are understood as a payment adjustment under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)), they are subject to that section's budget neutrality constraints. And to the extent these payments are understood as a payment under section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)), we explained that they are ''[a]dditional expenditures resulting from'' paragraph (t)(14) of the Act for years other than 2004 or 2005 and thus are subject to budget neutrality constraints under section 1833(t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(14)(H)).

We noted that this reading of these provisions is consistent with the statute's general approach of budget neutralizing OPPS payment adjustments, *see, for example,* section 1833(t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(9)(B)), except when expressly

[10] Throughout the duration of the policy, the 340B payment adjustment did not apply to critical access hospitals, rural sole community hospitals, children's hospitals, and PPS exempt cancer hospitals.

[11] Subparagraph (A) reads: Periodic review.—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

exempted, *see* sections 1833(t)(7)(I), (t)(14)(H), (t)(16)(D)(iii), (t)(18)(C), (t)(19)(A), (t)(20) of the Act (42 U.S.C. 1395*l*(t)(7)(I) (t)(14)(H), (t)(16)(D)(iii), (t)(18)(C), (t)(19)(A), (t)(20)). Budget neutrality in OPPS serves the important interest of limiting expenditures under Part B and thus protecting the public fisc. *Cf.* H.R. Rep. No. 106–436, at 33–34 (1999) (noting the goal of prospective payment systems, including the OPPS, is to slow growth rate of Medicare expenditures).[12] The Supplementary Medicare Insurance Trust Fund (hereinafter referred to as the Part B Trust Fund) that makes OPPS payments is mostly financed by premiums from participants and contributions from the general fund of the Treasury. We pointed to the Trustees' of the Part B Trust Fund warning that unexpected increases in Medicare Part B or D expenditures may require increases to beneficiary premiums and coinsurance, which already represent a growing share of beneficiaries' total income and are projected to reflect about three-quarters of the average Social Security retired-worker benefit by the end of this century. *See* The 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds at 40–41.[13] Additionally, unexpected increases in Medicare Part B or D expenditures could require tax increases or expenditure reductions elsewhere in the Federal budget; the Trustees already project expenditures to consume more than 30 percent of Federal income tax revenue in just 50 years. *Id.* at 43.

Accordingly, we summarized that when changes to payment policy are made, we generally make an adjustment to the OPPS conversion factor in order to maintain budget neutrality. (*See* 70 FR 68542 (noting outpatient drugs are included in the budget neutrality calculation beginning in 2006).) We do not believe the Congress intended the statute to permit regulated entities to achieve policy outcomes through litigation that would be statutorily unavailable to them through the regular rulemaking process, especially policy outcomes that increase total Medicare expenditures.

We acknowledged that, in the past, not all OPPS payment policy changes based on sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(14) and (t)(2)(E)) have resulted in adjustments to the budget neutrality factor or actual expenditures from the Part B Trust Fund equaling zero in all circumstances. We stated that the method CMS uses to account for changes to the ''estimated number of expenditures'' referenced in section 1833(t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(9)(B)) and incorporated by section 1833(t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(14)(H)) is the OPPS conversion factor (for example, 71 FR 68193 through 68194). We explained that in situations that have not had any estimated impact on the OPPS conversion factor or that would otherwise have a *de minimis* impact, such as a 0.0001 change to the conversion factor, which would have an inconsequential effect on Medicare payments, CMS has effectively rounded the estimated impact on expenditures to zero.[14] Thus, in circumstances when there would be a *de minimis* impact on estimated OPPS payment to meet the budget neutrality requirements as a result of a post-annual-rulemaking policy change, we have not changed OPPS payments to reflect the minimal impact of the policy change. When considering whether the estimated amount of expenditures is *de minimis,* we have taken into account relevant context, such as the size of the change comparable to the OPPS payments overall, the relative number of interested parties and any reliance interests, as well as the anticipated impact on the Part B Trust Fund of the change in payment due to the post-annual rulemaking policy versus the anticipated administrative burden and cost of ratesetting disruption.

We then applied these principles to the remedy payments for the 340B Payment Policy, concluding that a budget neutrality adjustment is statutorily required and, even if not statutorily required, warranted as a matter of sound public policy. The estimated impact of our one-time lump sum remedy payments is significant and reflects a substantial fraction of total OPPS spending for any one calendar year, one that goes well beyond any impact of which we have previously rounded to zero. The specifics of the lump sum are discussed in greater detail in the following section, II.B.1 of this final rule. Additionally, we noted that reliance interests or administrative burdens would not outweigh the impact of the remedy payments on the Part B Trust Fund sufficiently to justify disregarding the principle of budget neutrality, even if that were statutorily possible. We further explained that the potential reliance interests implicated by the need to recover unwarranted payments made over many years, combined with the unique difficulties in calculating and collecting these payments through retroactive rulemaking, should properly affect the way the budget neutrality principle applies to these unique circumstances.

We noted that we budget neutralized the 340B Payment Policy from CY 2018 to CY 2022 by increasing the rate for non-drug items and services by 3.19 percent. *See also* section I.A.3 of this final rule. That resulted in $7.8 billion in additional spending on non-drug items and services during that time period. We acknowledged that some OPPS providers were still filing, or re-filing, claims for CY 2022; therefore, our estimate of the total amount of additional spending on non-drug items and services during that time period could change as more claims from CY 2022 are processed, or reprocessed. As of this final rule, that number still rounds to $7.8 billion, but is more precisely $7,768,568,239. To assist readers, we will refer to this number as $7.8 billion throughout this document. We cited our consistent statements in both litigation and OPPS rules in the **Federal Register** that any remedy payments could be subject to budget neutrality constraints. *See, for example, Am. Hosp. Ass'n,* 142 S. Ct. at 1903 (acknowledging HHS's position that ''a judicial ruling invalidating the 2018 and 2019 reimbursement rates for certain hospitals would require offsets elsewhere in the program''); 84 FR 61323 (''Recognizing Medicare's complexity in formulating an appropriate remedy, any changes to the OPPS must be budget neutral, and reversal of the policy change, which raised rates for non-drug items and services by an estimated $1.6 billion for 2018 alone, could have a significant economic impact on the approximate[ly] 3,900 facilities that are paid for outpatient items and services covered under the OPPS.''). Additionally, because the 340B Payment Policy this rule proposed to remedy was itself budget neutralized, failing to budget neutralize the remedy payments would

[12] *https://www.govinfo.gov/content/pkg/CRPT-106hrpt436/pdf/CRPT-106hrpt436-pt1.pdf.*

[13] *https://www.cms.gov/oact/tr/2023.*

[14] In the CY 2007 OPPS/ASC final rule with comment period, using our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E), we implemented a quality improvement program which required hospitals eligible to participate in the Inpatient Prospective Payment Systems (IPPS) Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU) to meet the requirements for receiving the full FY 2007 IPPS payment in order to qualify for the CY 2007 OPPS update. Hospitals failing to meet the requirements would receive a reduced OPPS conversion factor update in CY 2007, the amount of which would then, if not deemed ''negligible,'' be offset by a corresponding increase to the OPPS conversion factor to maintain budget neutrality. See 71 FR 68193 through 68194.

mean that the additional payments for non-drug items and services that were made from CY 2018 through CY 2022 to achieve budget neutrality for the 340B Payment Policy as described under section I.A.3 of this final rule would be a windfall, especially to non-340B hospitals that were not subject to decreased drug payments from CY 2018 through CY 2022. The Trust Fund has a strong interest in recovering that windfall, and those who received it have no legitimate reliance interest in permanently retaining that windfall.

We also considered the administrative burden specific to maintaining budget neutrality noting CMS was already obliged on remand to remedy the 340B policy. We concluded that the decision to include a budget neutrality component in this remedy does not appreciably change this burden, though of course the burden could be greater or lesser depending on how the remedy is crafted. As set forth more fully below, our proposed budget neutrality adjustment does not directly recoup money already paid to providers; rather, it is a proposed adjustment to future payment rates, allowing hospitals to take such rates into account rather than forcing them to open their bank accounts and disgorge their windfall immediately. On balance, the billions of dollars the proposed payments to affected 340B covered entity hospitals would cost the Part B Trust Fund outweigh the potential administrative expenses or disruption resulting from a broad change in OPPS payment to offset these additional costs.

Finally, even if this remedy rule were exempt from budget neutrality requirements as a matter of statutory interpretation, we noted that we would still exercise our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) to offset the extra payments we made for non-drug items and services from 2018 through 2022. Those payments have proven to be an unwarranted windfall, and the Trust Fund has a strong interest in recovering them. We identified that avoiding a windfall to providers would also be consistent with the agency's longstanding inherent and common-law (and common-sense) recoupment authority, through which ''the Secretary generally has the duty and power to protect against overpayments to providers.'' *Chaves Cnty. Home Health Serv., Inc.* v. *Sullivan,* 931 F.2d 914, 918 (D.C. Cir. 1991); *see also, for example, United States* v. *Lahey Clinic Hosp., Inc.,* 399 F.3d 1, 16 (1st Cir. 2005) (''Although provisions of the Medicare Act expressly authorize the Secretary to reopen initial payment determinations and to recoup overpayments administratively in certain circumstances, the statute does not displace the United States' long standing power to collect monies wrongfully paid through an action independent of the administrative scheme, nor is there any inconsistency.'' (internal citations omitted)); *Mount Sinai Hosp. of Greater Miami, Inc.* v. *Weinberger,* 517 F.2d 329, 345 (5th Cir.), *modified,* 522 F.2d 179 (5th Cir. 1975) (similar). For that reason and those discussed above, unwinding those payments is necessary to ensure equitable payments under these circumstances.

Therefore, we concluded that it is required by the statute—but even if not required, that it would be consistent with the statute—and consistent with our past practices, and appropriate, to offset the additional payments for non-drug items and services that were made from CY 2018 through CY 2022 in order to maintain budget neutrality or equitable payments when remedying this policy. But the context of this rule, we clarified, remains unique: We are adjusting payments prospectively in order to provide a remedy for a previous unlawful payment decision. Precisely because that previous payment decision itself followed budget neutrality principles, it provided unwarranted payments to some at the same time it improperly took payments from others. In applying budget neutrality principles to this remedy, we seek to rectify this imbalance and restore matters as closely as possible to where they would have been absent the policy the Supreme Court determined to be unlawful. We solicited comments from the public on our proposed interpretation of our statutory budget neutrality obligations, equitable payment authorities, and recoupment authority.

Comment: We received many comments on our proposed interpretation of our statutory budget neutrality obligations, equitable payment authorities, and recoupment authority.

Response: These comments are addressed in section II.B.2.b of this final rule.

2. Full Claims Reprocessing From CY 2018 Through September 27th of CY 2022

In the proposed rule (88 FR 44082), we explained that perhaps the most perfect measure of achieving budget neutrality in circumstances like this would be to turn back the clock to the day the unlawful payment decision was first made, undo that decision, and start over. We identified that CMS would have to reprocess all OPPS claims for 340B-acquired drugs and non-drug items and services from CY 2018 through September 27th of CY 2022 using the default payment rate under section (t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)) and our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)). This approach would have the benefit of putting providers, beneficiaries, and Medicare back in the same situation they would have been in if CMS had never adopted the ASP minus 22.5 percent rate for 340B-acquired drugs in 2018. But remedial rulemaking need not provide this type of precise make-whole relief. *See Shands Jacksonville Med. Ctr., Inc.* v. *Azar,* 959 F.3d 1113, 1118 (D.C. Cir. 2020) (agreeing that the agency need not restore ''each individual hospital . . . at least to the position it would have occupied had the rate reduction never taken effect'').

We acknowledged that reprocessing every single claim might be a potential approach to remedy this situation if it were administratively achievable. But we feared that reprocessing such an unprecedentedly large volume of claims and issuing payment to affected 340B covered entity hospitals in a timely fashion would impose an immense administrative burden on CMS, its contractors, and providers. We accordingly concluded that this approach is not feasible in this case. It would require the reprocessing of virtually all claims submitted to the OPPS system during the affected period of time, but that system processes more than 100 million claims each year. We remarked that reprocessing almost 5 years' worth of OPPS claims could take several years, resulting in some affected 340B covered entity hospitals having to wait multiple years to receive payment, and leading to widespread beneficiary cost sharing uncertainty, as beneficiaries could be caught by surprise by a significant change in cost sharing responsibility from a claim they thought had been closed many years ago. The large quantity of claims and the amount of time required to reprocess them while continuing normal claims processing likewise would not result in timely payments or adjustments to hospitals. Additionally, we indicated that reprocessing these claims would lead to the need for significant recoupments of payments for non-drug items and services that would have already been paid at the higher rate based on the budget neutrality adjustment applied as a result of the original 340B Payment Policy. The D.C. Circuit has held that it

is not necessary ''to recalculate each individual claim paid under the reduced rate'' that was the subject of litigation when doing so would cause significant administrative burden and delayed payments. *See Shands,* 959 F.3d at 1120. But we did allow that the expected results of such a calculation can certainly inform an alternative approach to budget neutrality, as we discuss below.

We noted that the vast majority of 340B drug claims from CY 2022 have been reprocessed at the higher 340B payment rate, generally ASP plus 6 percent, which we believe was allowable under the District Court's order prospectively vacating the CY 2022 340B payment rate and the typical timely filing requirements described at 42 CFR 424.44. We confirmed this was appropriate for CY 2022 claims given that providers were able to follow the regular claims processing conventions for these claims, and clarified that we will ensure CMS does not make duplicate payments for these claims already remedied by the usual claims processing methods. As part of this final rule, we estimate that for CY 2022, $1.6 billion in remedy payments (including the Medicare and beneficiary portions) have already been made to providers through reprocessed claims, or claims that had dates of service of January 1, 2022, through September 27, 2022, but were held until, or reprocessed after, the 340B rule was vacated and the standard drug payment rates were in effect for 340B-acquired drugs. We consider these reprocessed claims to be partially remedied as 340B providers no longer received the lower 340B drug payment rate for these 340B-acquired drugs. This $1.6 billion is one component of the total remedy payments accounted for in this final rule. We also note that these claims only had the 340B drug portion of the claim adjusted, and that for these claims to be fully remedied the non-drug item and service components of these claims would also need to be adjusted as discussed in subsequent sections.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: Commenters generally agreed with CMS's conclusion that reprocessing all claims is not administratively feasible. Commenters appreciated that CMS considered this option but did not formally propose it in the proposed rule.

Response: We appreciate commenters' concurrence with our conclusion.

Comment: One commenter requested that CMS pay providers that elected to submit adjusted claims for dates of service between January 1, 2022, through September 27, 2022, the beneficiary copayment amount for those claims. The commenter points out that providers who elected not to submit adjusted claims for those dates of service will receive both the Medicare portion and the beneficiary copayment portion through the remedy payment. Failing to pay the beneficiary copayment amounts for providers that elected to submit adjusted claims, the commenter argues, results in different remedies for the beneficiary portion for providers that submitted adjustment claims and those that did not submit adjustment claims, which is an inequitable outcome.

Response: We do not agree that CMS should pay providers that elected to submit adjusted CY 2022 claims additional payment for beneficiary cost sharing. We are paying amounts equal to *lost* beneficiary cost sharing amounts providers are not otherwise legally entitled to collect based on a finding that, under the unique circumstances of this rule, it is necessary to ensure equitable payments under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)). (See infra at II.B.1.e.) Because CY 2022 adjustments followed regular claims processing conventions, providers are legally entitled to collect cost sharing from beneficiaries on those claims. If providers are unable to do so, such payments would be subject to our usual standards governing payments to which providers are legally entitled but unable to collect. *See, for example,* 42 CFR 413.89. We thus do not believe the same rationale applies to reprocessed claims.

Permitting providers to submit adjustment claims also allowed for prompt payment to providers and partially approximated how the claim would have been processed and paid absent the 340B Payment Policy. Indeed, many of these claims have already been finalized and the beneficiaries have paid their cost sharing obligation. Because providers can collect cost sharing for reprocessed CY 2022 claims from beneficiaries and potentially under our bad medical debt regulations, we do not believe it would be equitable under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) to make additional, potentially duplicative payments to reflect lost cost sharing.

As described in the proposed rule, we considered these reprocessed claims to be partially remedied as 340B providers no longer received the lower 340B drug payment rate. These claims will be fully remedied when we address the non-drug item and service payment portion of these claims.

Comment: CMS received several comments requesting a mass reprocessing of all CY 2022 claims and instructions to the Medicare Administrative Contractors (MACs) to make one mass adjustment for claims going back to January 1, 2022.

Response: We do not have an existing procedure to make the mass adjustment commenters proposed for CY 2022 claims without reprocessing each individual claim, and we believe that our proposed lump sum payment achieves a very similar result. While reprocessing just the remaining CY 2022 claims would be less burdensome than reprocessing all claims back to 2018, it would still impose a large administrative burden on CMS, our contractors, and providers. Approximately two hundred million dollars worth of payments would have to be reprocessed, and, importantly, such an undertaking could cause an additional delay in making payments relative to the proposed lump sum payment methodology. Otherwise, the main practical difference between reprocessing the remaining CY 2022 claims or including them in the lump sum payment is whether providers can seek cost sharing payments from beneficiaries, as discussed above. But because we have increased the lump sum payment under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) to cover lost beneficiary cost sharing, we do not view that as a material difference between the options. Because including remaining CY 2022 claims in the one-time lump sum payment will provide nearly equivalent remedy funds to affected 340B covered entity hospitals, and will do so more quickly and efficiently than a mass reprocessing of all CY 2022 claims, we decline to treat remaining CY 2022 claims differently from other claims years.

3. Aggregate Hospital Payments From CY 2018 Through September 27th of CY 2022

In the proposed rule (88 FR 44083), we considered calculating one-time aggregate payment adjustments for each provider for the CY 2018 through September 27th of CY 2022 time-period, including both additional payments for 340B-acquired drugs and reduced payments for non-drug items and services under sections 1833(t)(2)(E) and 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(2)(E) and (t)(14)), along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42

U.S.C. 1395hh(e)(1)(A)), to the extent the policy would be retroactive. This option would have involved: (1) calculating the total additional payments for each hospital that would have been paid for separately payable non-pass-through 340B-acquired drugs from CY 2018 through September 27th of 2022 in the absence of the 340B Payment Policy; (2) calculating the additional amount each hospital was paid under the OPPS from CY 2018 through CY 2022 for non-drug items and services as a result of the 340B policy; (3) subtracting (2) from (1); and (4) issuing a payment to, or requiring a recoupment from, each hospital for the 5-year period in which the 340B Payment Policy was in effect. This is similar to the approach we ultimately adopt in this rule, except that it would have effectively implemented budget neutrality requirements through an immediate lump sum *recoupment* that would mirror the lump sum remedy *payment.*

While this approach would also have satisfied the statutory budget neutrality concerns discussed above, we did not read the statute to mandate such an inflexible approach in these circumstances. *Cf. Shands Jacksonville Med. Ctr., Inc.,* 959 F.3d at 1120. (For further discussion of this point, see section II.B.1.a of this final rule.) Such an approach would require immediate, and in many cases large, retroactive recoupments from the majority of OPPS hospitals and would impose a substantial, immediate burden on these hospitals as well as an uncertain impact on beneficiaries. After accounting for these burdens, the financial strain many hospitals experienced during the recent COVID–19 public health emergency (hereinafter referred to as the ''PHE''), and the amount of time that has transpired since the original payments for these drugs, items, and services were made, we decided not to propose this option as our suggested approach.

Comment: Several commenters expressed general support for our decision not to propose a one-time aggregate payment adjustment for each provider.

Response: We thank commenters for their support.

B. Remedy

1. Methodology for Calculating and Process for Remitting Remedy Payments to Affected 340B Covered Entity Hospitals for 340B-Acquired Drugs Furnished and Paid Adjusted Amounts Under the OPPS in CY 2018 Through September 27th of CY 2022

a. Statutory Authority

In the proposed rule (88 FR 44083), we stated that CMS believes that the best way to remedy our 340B Payment Policy for the period from CY 2018 through September 27th of CY 2022, which the Supreme Court found unlawful, would be to make one-time lump sum payments to affected 340B covered entity hospitals calculated as the difference between what they were paid for 340B drugs (ASP minus 22.5 percent or an adjusted WAC or AWP amount) during the relevant time period (from CY 2018 through September 27th of CY 2022) and what they would have been paid had the 340B Payment Policy not applied. We explained that this approach comes as close to providing 340B-covered entities with make-whole relief as CMS can reasonably accomplish, without the burden that would be associated with manually reprocessing all claims. Assuming hospitals properly assigned the billing codes discussed below when submitting their CY 2018 through 2022 claims, as they were required to do, CMS noted that it expects the remedy payment to each 340B covered entity for 340B-acquired drugs to be approximately the same as if CMS manually reprocessed those claims. Calculating the approximate repayment amount based on claims data is relatively straightforward administratively as it involves only an aggregated analysis of the claims in question, whereas reprocessing all claims requires significantly more administrative effort as the claims actually have to be individually reprocessed through the claims processing system. This is practically infeasible for the reasons discussed earlier in this rule. Please see the previous section titled ''Full Claims Reprocessing from CY 2018 through September 27th of CY 2022'' for additional detail.

We proposed to make the remedy payments relying principally on (1) our rate-setting authority under section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)); and (2) our equitable adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)). To the extent this rule is retroactive (in whole or in part), we explained that we would rely on our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)).

First, we evaluated our authority under section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)). We pointed to the Supreme Court's holding that if CMS has not conducted a survey of hospitals' acquisition costs, the agency may not vary the payment rates for outpatient prescription drugs by hospital group. We acknowledged that because we did not use any survey of hospitals' acquisition costs when setting rates for 340B-acquired drugs between CY 2018 and September 27, 2022, it is necessary for the remedy to apply the default rate (generally ASP plus 6 percent) to comply with paragraph (14)(A)(iii) of section 1833(t) of the Act (42 U.S.C. 1395*l*(t)(14)(A)(iii)) for those years, as interpreted by the Supreme Court.

We then considered our authority to adjust the prior payment rate. We explained that section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)) prohibits a substantive change in regulations to items and services furnished before the effective date of the substantive change unless ''such retroactive application is necessary to comply with statutory requirements'' or the ''failure to apply the change retroactively would be contrary to the public interest.'' We explained that, assuming this remedy is viewed as a retroactive remedy (in whole or in part), it would also be necessary to use this retroactive rulemaking authority to implement the remedy by revising 340B payment rates for this prior period to comply with the Supreme Court's interpretation of the requirements of section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)).

But even if a retroactive rule were not necessary specifically to comply with section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)), we found that failing to apply the default rate retroactively would be contrary to the public interest in this specific situation in part because it would leave the plaintiff 340B hospitals paid at a substantially lower rate, due to the magnitude of payment, than we now understand to be proper under the statute. We found that the equities weigh in favor of a partially retroactive remedy here, because a significant number of plaintiff hospitals have been advocating for this current policy in court since we first announced our 340B Payment Policy for CY 2018 despite our view that there was no administrative or judicial review for such claims. The equities further align with a partially retroactive remedy, to the extent required, because the impact on the Part B Trust Fund will be

lessened as we are applying budget neutrality principles. We noted that the position of those plaintiff hospitals was ultimately vindicated by the Supreme Court.

We proceeded to consider our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)), which requires the Secretary to, ''establish, in a budget neutral manner, outlier adjustments . . . transitional pass-through payments . . . and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.'' In this case, we proposed that the lump sum payment, calculated as the difference between what an affected 340B covered entity hospital received for 340B-acquired drugs during the time period at issue and what they would have received for 340B-acquired drugs if the 340B adjustment had not been in place, would be an equitable adjustment. We found that such an adjustment is necessary to ensure equitable payments to affected 340B covered entity hospitals by making them whole for the decreased payments for 340B-acquired drugs they received from CY 2018 through September 27th of CY 2022 that are no longer proper in light of the Supreme Court's decision. To the extent necessary, we explained we would apply the adjustment retrospectively in accordance with the Court's ruling and for the reasons discussed in the above paragraph.

We therefore proposed to use our authority under section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)) in conjunction with our equitable adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)), to accomplish an equitable outcome as we remedy past payments made under the 340B Payment Policy. To the extent necessary, we also proposed to use our retroactive rulemaking authority under section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)).

We solicited comment from the public on our proposed use of these authorities in the remedy policies discussed in the proposed rule. We also solicited comment on other possible authorities (including inherent authority or common law authority) that might also be applicable to the remedy policies discussed in the proposed rule or on which we could rely to make remedy payments.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: Nearly all commenters supported our proposal to pay via a one-time lump sum payment.

Response: We appreciate commenters' support.

Comment: Several commenters encouraged CMS and MACs to agree on documentation and treatment of these funds on cost reports, cost report audits, and subsequent Medicare payment adjustments and reviews.

Response: We agree that it is important to coordinate with MACs to ensure consistent documentation and treatment of the one-time lump sum payments. These payments will not be made on cost reports. To ensure timely payment for all impacted providers, CMS shall issue guidance to all MACs to allow consistent documentation and tracking of the 340B payments.

Comment: Two commenters opposed our proposal to pay via a one-time lump sum payment due to concerns that a massive influx of funds to 340B hospitals would enable those hospitals to further dominate local markets by purchasing independent community clinics and other hospitals. One of these commenters requested that repayments be spread out over time, suggesting 5 years for this time-period or, alternatively, 16 years to align it with the budget neutrality adjustment schedule discussed later in this rule. The other commenter suggested that CMS provide remedy funds for 2018 to 2020 and use a 340B drug acquisition cost survey to determine the remedy payments for subsequent years.

Response: We appreciate commenters' concerns. As previously discussed, the aim of this rule is to situate all OPPS providers as closely as possible to the financial situation they would have been in if the 340B OPPS Payment Policy had never existed. Had we never implemented the 340B Payment Policy, hospitals would already have these payments. We thus believe the fairest policy is to pay hospitals as promptly as administratively feasible. We acknowledge that this means that until the budget neutrality adjustment is fully implemented, hospitals will temporarily have additional funds from our payments for non-drug services and items they would not otherwise have had. But commenters have not identified authority requiring us to withhold payments based on competition concerns once we have determined the amount due from Medicare. As such, we believe the payment timeline described in this rule is appropriate.

We acknowledge that we previously suggested that we might use our survey of CY 2018 and 2019 cost data to inform the remedy as discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61322). But as we subsequently noted, we received many comments on the survey data, and using that data, which surveyed only 340B hospitals, might not comport with the Supreme Court's decision. Using it would introduce new complexities into the rate calculation, for instance, by requiring consideration of adjustments to the data and other factors as discussed in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86052). We do not believe it is worth delaying the remedy payments to allow for such considerations or for us to conduct a new survey many years after the fact.

Comment: We received many comments on the statutory authority we proposed to rely upon to make lump sum payments. While nearly all commenters supported our proposal to implement this remedy via a one-time lump sum payment, industry commenters disagreed with our proposal to rely on sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(14) and (t)(2)(E)) to do so. Many of these commenters argued that these statutory provisions do not apply to the remedy payments. These commenters stated that CMS is attempting to rely on statutes designed for, and limited to, making prospective adjustments to spending estimates, or discretionary adjustments based on equity to make remedy payments required by the Supreme Court's decision.

With respect to section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)), these commenters maintained that the expenditures to which the statute applies do not contemplate court-ordered remedy payments. Referencing the text of section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)), ''[a]dditional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years,'' these commenters argue that the proposed lump-sum payment is neither an ''additional'' expenditure nor an expenditure ''resulting from this paragraph.'' In their view, there is nothing additional about the lump sum payment, it is what 340B hospitals should have been paid in the first place and the payment is not being made as a result of this paragraph but rather the agency's loss of a court case. One commenter argued that the additional expenditures are those that could result from CMS electing to refine its payment methodology as permitted

under section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)). The commenter shared that this means performing a survey and changing the drug payment methodology or refining the overhead cost payment. In this case, they stated that the additional expenditures are neither of these and are instead ''a loss at the Supreme Court, not a payment methodology refinement.''

With respect to section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)), which provides the Secretary with the authority to establish, ''in a budget neutral manner, outlier adjustments . . . and transitional pass-through payments . . . and other adjustments as determined to be necessary to ensure equitable payments,'' commenters argued that this provision is not applicable to the remedy payments because, in their view, CMS is not exercising any payment discretion (but is required to make the payments) and the payments are not being made for equitable reasons (but to comply with a court judgment) and, like section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)), the provision is purely prospective in nature. Commenters suggested that in the introductory text of subsection section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)), ''under the payment system'' refers to the prospective payment system addressed in section (t) as a whole: ''Prospective Payment System for Hospital Outpatient Department Services'' and section 1833(t)(2)(E) of the Act's inclusion within that system prohibits its use for recoupments. One commenter argued that CMS construes ''adjustment'' too broadly and that its meaning under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) refers to outliers and transitional pass-through payments, which the commenter characterizes as ''cornerstone features'' of the outpatient prospective payment system.

Many commenters argued that if section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) did apply to the proposed lump sum payments, that the amount of the payments is too large to qualify as an adjustment under the statute. In support of this position, these commenters referenced *Biden* v. *Nebraska,* 143 S. Ct. 2355, 2368 (2023), which interpreted the term ''modify'' in a different statute to mean ''to change moderately and in minor fashion.'' According to the commenters, the D.C. Circuit has interpreted HHS's adjustment authority to have the same limits that the Supreme Court found in the word ''modify'' in other contexts, and the remedy payment here is too large to qualify. *See Amgen, Inc* v. *Smith.,* 357 F.3d 103, 117 (D.C. Cir. 2004). These commenters agreed that CMS may use section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) to increase the remedy payments by $1.8 billion (the amount of beneficiary cost sharing).

Response: We continue to believe that we should rely on sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(14) and (t)(2)(E)) to make these remedy payments. No commenter identified any alternate statutory authority on which we could rely, and we disagree with commenters' arguments that these provisions are inapplicable. While we agree that section 1833(t) creates a prospective payment system, *see* section 1833(t)(1)(A) of the Act (42 U.S.C. 1395*l*(t)(1)(A)), the Supreme Court declined to find this fact foreclosed all retrospective review. *Cf. Am. Hosp. Ass'n* v. *Becerra,* Br. for Respondents at 21–22 (government brief arguing the statute foreclosed '''administrative or judicial review of the prospective payment system,' '' and noting invalidation of an OPPS component '' 'could result in the retroactive ordering of payment adjustments' '' (quoting H.R. Rep. No. 149, 105th Cong., 1st Sess. 724 (1997) (House Report) *and Amgen, Inc.,* 357 F.3d at 112)). Indeed, at least one court has rejected an argument that CMS lacks the authority to make retroactive adjustments when required to comply with other provisions in section 1833(t) of the Act (42 U.S.C. 1395*l*(t)). *See H. Lee Moffitt Cancer Ctr. & Rsch. Inst. Hosp., Inc.* v. *Azar,* 324 F. Supp. 3d 1, 16 (D.D.C. 2018) (''HHS has not shown that such a retroactive adjustment would be incompatible with the generally prospective nature of OPPS.'').

We disagree with commenters that stated that a court has ''ordered'' payments, or that court-ordered payments necessarily fall outside of section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)). No court has yet weighed in on the appropriate remedy, much less ordered any particular payment. *See, for example, Am. Hosp. Ass'n,* 2023 WL 143337, at *3 (rejecting argument that court should order agency to ''repay[] those hospitals that were unlawfully underpaid, from 2018 to the present, the difference between what they were paid and ASP plus 6%'').

We also disagree that our remedy payment is not ''equitable'' within the meaning of section (t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) simply because it remedies legal error. Ensuring that providers are paid according to Congress' policy judgments is a legitimate way to ensure fairness, in the most common meaning of the term ''equitable.'' Indeed, to the extent the term ''equitable'' under section (t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) might be informed by courts' historic equitable authority, the fact that we are seeking to restore parties to as close a state as they would have been without the now-invalidated 340B Payment Policy makes the rule analogous to historic equitable remedy of recession and restitution. *See* Restatement (Third) of Restitution and Unjust Enrichment section 54 (2011) (''[T]he expression ''rescission and restitution'' aptly describes cases in which the claimant may be restored to the status quo ante by obtaining the fungible equivalent of personal property previously transferred to the other party.'').

Nor do we agree with commenters that this rule exceeds our statutory authority to make ''adjustments'' to the payment system ''as determined to be necessary to ensure equitable payments'' under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)). Both the Supreme Court and the D.C. Circuit have declined to define the outer bounds of that term. *See Am. Hosp. Assoc'n,* 142 S. Ct. at 1904 (''[W]e need not determine the scope of HHS's authority to adjust the price up or down.''); *Amgen, Inc.,* 357 F.3d at 117 (''[T]he court has no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments.' ''). While we acknowledge that the Supreme Court has held that in certain contexts the statutory authority to ''modify'' a program limits the amount by which an agency can change the program, we believe the statutory term ''adjustment'' has a different focus here. For example, in *Nebraska,* when construing the term ''modify,'' the Supreme Court relied in part on Black's Law Dictionary's definition of modify which built in ''a connotation of increment or limitation.'' 143 S. Ct. at 2368 (citing MODIFY, Black's Law Dictionary (11th ed. 2019) (''To make somewhat different; to make small changes to (something) by way of improvement, suitability, or effectiveness'').) But that same dictionary defines ''adjustment'' to focus on adapting something to better apply in a particular circumstance. ADJUSTMENT, Black's Law Dictionary (11th ed. 2019) (''That which adapts one thing to another or to a particular use''). We therefore believe our adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(2)(E)) fairly encompasses adapting generally prospective payments to remedy legal errors made in those payments. And even if adjustment carries a connotation

of increment or limitation, the 28.5 percent adjustment this final rule makes to the payments made to hospitals for 340B-acquired drugs would not exceed it. The cases in which the Supreme Court has found that agencies exceeded their modification authority are those where the Court found that there was a change in kind to the affected program, not simply a change in degree. *See Nebraska,* 143 S. Ct. at 2369 (changes exceeded modification authority when agency ''created a novel and fundamentally different loan forgiveness program''); *MCI Telecommunications Corp.* v. *Am. Tel. & Tel. Co.,* 512 U.S. 218, 230 (1994) (changing statute ''from a scheme of rate regulation in long-distance common-carrier communications to a scheme of rate regulation only where effective competition does not exist'' exceeded modification authority); *cf. also Amgen, Inc.,* 357 F.3d at 117 (adjustment does not include a ''total elimination or severe restructuring of the statutory scheme''). Here, CMS is adjusting payment rates back to their default under the statute. Restoring a default payment provision is the opposite of the implementation of ''a new regime entirely'' that the Supreme Court has invalidated.

We acknowledge that we are in a somewhat unique situation. We have generally operated the OPPS system based on a belief that its prospective payments were insulated from administrative and judicial review. In light of the Supreme Court's decision, however, we must find a way to reconcile a primarily *prospective* budget neutral rate-setting system with adjudication processes that are generally *retrospective* in nature. Here, it is enough for us to find that sections 1833(t)(14) and (t)(2)(E)—and section 1871(e)(1)(A), to the extent required—authorize us to correct the legal error identified by courts in our prior payments under section 1833(t)(14).

Comment: One commenter argued that CMS could not rely on its retroactive rulemaking authority under section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)), in conjunction with sections 1833(t)(2)(E) and (t)(14) of the Act (42 U.S.C. 1395*l*(t)(2)(E) & (t)(14)), to make the remedy payments because section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)) prohibits retroactive rulemaking except for two limited exceptions, neither of which apply to the remedy payments. The first exception cited by the commenter applies to situations in which ''retroactive application is necessary to comply with statutory requirements'' (see section 1871(e)(1)(A)(i) of the Act) (42 U.S.C. 1395hh(e)(1)(A)(i)) and the second to situations in which ''failure to apply the change retroactively would be contrary to the public interest'' (see section 1871(e)(1)(A)(ii) of the Act (42 U.S.C. 1395hh(e)(1)(A)(ii)). Concerning the first exception, the commenter contends that the proposed rule discusses retroactive rulemaking authority only with respect to the drug payment methodology for 340B-acquired drugs and makes no argument that payments for non-drug items and services may be changed retroactively or that CMS may retroactively re-estimate its budgetary projections from 2018. The commenter concludes that because the OPPS is expressly required to be prospective in nature, ''retroactive adjustments'' to past years' payment rates are not ''necessary to comply'' with statutory requirements of the OPPS. Concerning the second exception, the commenter argues that it is not in the public interest to engage in the retroactive adjustment of prospective payment rates (particularly when doing so would upset the reliance interest of all hospitals with respect to payment for non-drug items and services) when make-whole relief can be implemented without revisiting 2018 through 2022 OPPS rates.

Response: We disagree with the commenter that the OPPS's generally prospective nature implicitly overrides CMS's retroactive rulemaking authority under section 1871(e) of the Act (42 U.S.C. 1395hh(e)). The Supreme Court held (in 2022) that we lacked authority (in 2018) under section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)) to set a payment rate of ASP–22.5 percent for 340B-acquired drugs absent a drug acquisition cost survey. Thus, to the extent we are acting retrospectively in this rule, conforming payment rules that are still on the books and still contain a payment rate contrary to the requirements of section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)) would be a classic case where retroactive rulemaking would be ''necessary to comply'' with statutory requirements. As noted above, courts have rejected the argument that because section 1833(t) of the Act (42 U.S.C. 1395*l*(t)) establishes a prospective payment system, that system is not subject to any retrospective review or amendment. And because the payment *increases* for non-drug items and services for those years were inextricably linked to the illegal payment *decreases* for 340B-acquired drugs, the same reasoning would apply. We are not, as commenter suggests, re-estimating our budget projections—a point we also discuss below in section II.B.2. Rather, we are unwinding a payment rate that courts held was illegal.

We also disagree with the commenter's public interest argument. As noted above, commenters have not identified any authority through which we could implement make-whole relief without relying on sections 1833(t)(14) or (t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(14) and (t)(2)(E)). And we disagree that hospitals' reliance interest undermines our interpretation here. Hospitals were aware that we believed their increased payments for non-drug items and services hinged on the payment decreases for 340B-acquired drugs. (No one, for example, has suggested we could retain the 3.19 percent payment increase in CY 2023 once we reverted to an ASP plus 6 percent payment rate for 340B acquired drugs.) Hospitals successfully convinced courts that those payment decreases are illegal, and it thus follows that the intertwined payment increases were unwarranted under the statute, as well. If the payment increases were not removed, the remedy payments would ultimately come from beneficiaries, taxpayers, or some combination of the two. The commenter's suggestion would effectively involve at least a $9 billion transfer from beneficiaries and taxpayers to hospitals, which would be inappropriate especially in a system where budget neutrality requirements generally prevent such transfers.

Comment: Many commenters claimed that CMS does not require any statutory authority to make the remedy payments and that it can make the payments using an ''acquiescence authority.'' Commenters point to past instances in which CMS has allegedly exercised the posited acquiescence authority, including Administrator rulings,[15] manual updates,[16] settlements with hospitals [17] and the processing and reprocessing of CY 2022 340B drug claims at the default drug rate for dates

[15] See CMS Ruling No. 1498–R.(Apr. 28, 2010). *https://www.cms.gov/regulations-and-guidance/guidance/rulings/downloads/cms1498r.pdf.*

See also CMS Ruling No. 1355–R.(Apr. 14, 2011). *https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads/cms1355r.pdf.*

[16] See CMS Pub. 100–20, Transmittal No. 10520 (Dec. 14, 2020). *https://www.cms.gov/files/document/r10520otn.pdf.*

[17] See HealthAlliance Hospitals, Inc. v. Azar, 346 F. Supp. 3d 43 (D.D.C. 2018); see also Clerk's Orders Granting Extensions To Accommodate Pending Mediation, dated March 26, 2019, April 18, 2019, and June 13, 2019, HealthAlliance Hosps., Inc. v. Azar, No. 18–5372 (D.C. Cir.); Joint Stipulation of Dismissal dated August 29, 2019, HealthAlliance Hosps., No. 18–5372 (D.C. Cir.).

See Cape Cod Hospital v. Sebelius, 630 F.3d 203 (D.C. Cir. 2011); see also 76 FR. 51476, 51799 (Aug. 18, 2011).

of service between January 1, 2022, and September 27, 2022, described in the proposed rule (''a large portion of the CY 2022 340B drug claims for dates of service between January 1, 2022, and September 27, 2022, have already been remedied as a result of being processed or reprocessed at the default drug payment rate.'').[18] Commenters argue that we are ignoring this acquiescence authority in order to justify the budget neutrality policy we discuss later in section II.B.2 of this final rule.

Response: We have previously explained that acquiescence is a choice by an agency, when faced with a lower court decision disagreeing with the agency's legal interpretation, to ''recognize that court's interpretation and apply the court's interpretation uniformly, thereafter, within the jurisdictional bounds of the interpreting court.'' *In the Case of: St. Vincent Mercy Medical Center Provider* v. *Blue Cross Blue Shield Association/national Government Services—Ohio Intermediary,* 2008 WL 6468508, at *9 (CMS Adm'r) (acquiescing to circuit court's interpretation of law for providers within the jurisdictional bounds of the deciding court). That makes the acquiescence doctrine an awkward fit here because it is most often applied to rulings from circuit courts, whose precedential authority is geographically limited and whose legal interpretations are subject to further review. The Supreme Court is not so limited, and its statutory interpretations are generally binding on parties with pending claims. *See Harper* v. *Virginia Dep't of Tax'n,* 509 U.S. 86, 97 (1993) (''When this Court applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law and must be given full retroactive effect in all cases still open on direct review.'').

Regardless, we do not understand acquiescence to be an independent source of authority or one that frees us from otherwise applicable statutory constraints, as commenters believe. Commenters' examples do not suggest otherwise. The cited Administrator rulings were routine applications of judicial precedent to pending administrative appeals. *See* CMS Ruling No. 1498–R, at 6 (Apr. 28, 2010) (limiting relief to providers with ''properly pending DSH appeal of the SSI fraction data matching process issue'' under section 1869 of the Act (42 U.S.C. 1395ff)); CMS Ruling 1355–R, at 8 (limiting relief to providers with ''properly pending appeals'' under section 1878 of the Act (42 U.S.C. 1395oo)). Such actions are contemplated by the agency's authority to ''affirm, modify, or reverse'' in pending adjudications. *See* section 1869(b)(1) of the Act (42 U.S.C. 1395ff(b)(1)) (incorporating authority under section 205(b) of the Act (42 U.S.C. 405(b)); 1878(f)(1) of the Act (42 U.S.C. 1395oo(f)(1) (same)). The decisions cited by commenters never suggest that we could issue payments that violate statutory limitations, nor have commenters identified any statutory limitations those decisions allegedly violated.[19] Neither payment adjustment in the two cited rulings, for example, were subject to a budget neutrality requirement. *See, for example,* 2014 IPPS Final Rule, 78 FR 50496, 50507 (2013) (noting statutory amendments resulting in reductions to DSH payments ''are not budget neutral''); Medicare Program; Hospice Wage Index for Fiscal Year 2010, 74 FR 39384, 39390–91 (2009) (rejecting notion that ''Medicare insists on budget neutrality in all of its payment systems''). To the contrary, several of the cited examples show that CMS enforces payment limits in prospective payment systems, even when acting retroactively or in response to disagreement by a court. *See* CMS Pub. 100–20, Transmittal No. 10520 (Dec. 14, 2020) (instructing contractors to recalculate graduate medical education payments to comply with annual payment caps under section 1886(*l*) of the Act (42 U.S.C. 1395ww(*l*)); [20] 76 FR 51476, 51788 (addressing payment issue relating to application of budget neutrality adjustment after court decision in *Cape Cod Hospital* v. *Sebelius,* 630 F.3d 203 (D.C. Cir. 2011) by ''remodel[ing] the recalibration/wage index budget neutrality factor for the years at issue''); *accord* Medicare Program; Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1991 Rates, 55 FR 35990, 36043 (1990) (''Absent a retroactive budget neutrality adjustment at the beginning of next fiscal year, we believe that we would be precluded from making mid-year corrections to the wage index since they could not be accomplished in a budget neutral fashion as required by law.'').

To be sure, the court in *H. Lee Moffitt Cancer Center* v. *Azar,* 324 F. Supp. 3d 1 (D.D.C. 2018), noted one prior instance where we had missed a small number of hospitals in our first year implementing budget neutral payment adjustments for certain rural hospitals and did not clearly budget neutralize a retroactive adjustment. *Id.* at 15 (citing 71 FR 67960, 68010). That court acknowledged that CMS had previously ''temporarily raised prospective rates in order to make up for reductions applied in prior years'' and so saw ''no reason why HHS could not do the converse here if it believed offsets were required: make a slight reduction in prospective rates for a future year to accommodate a retroactive adjustment'' for the single plaintiff hospital. *Id.* at 17 n.5. In any event, both the rural hospital adjustment issue and the cancer hospital issue involved relatively small adjustments to a single year of payments to a very limited number of providers, and one situation involved resolution through settlements with individual providers that had properly appealed the issue. When the additional rural hospitals (rural essential access community hospitals) were included in the rural hospital adjustment, the entire adjustments changed the budget neutrality factor by approximately 0.00002, which is so small of a change that it would only change payment rates by a fraction of a cent, and likely not change payment rates by a penny. (71 FR 68003). And while all eleven cancer hospitals impacted the budget neutrality factor by 0.0022 the year they were added—reflecting a total of $71 million of payment impact (76 FR 76,190)—only a few ultimately sued over the payments and the government resolved the matters through settlements with individual providers. *See H. Lee Moffitt,* 324 F. Supp. 3d at 9 (estimating $7.4 million payment impact for plaintiff hospital). These are the types of *de minimis* impacts that CMS has rounded to zero. We do not believe these two much smaller examples relieve us of our statutory obligations here, which involve several billion dollars and more than 3,600 hospitals, restructuring Medicare Part B payments for these drugs payments across 5 years-worth of claims. As we noted in the proposed rule, we are particularly concerned that adopting providers' position would allow them to use litigation as a workaround to otherwise applicable constraints on Medicare payments and

[18] See proposed rule at 88 FR 44088 (Nov. 13, 2017).

[19] We understand our approach to remedies to be consistent with how courts view their own remedy authority. *See, for example, Off. of Pers. Mgmt.* v. *Richmond,* 496 U.S. 414, 426 (1990) (''[J]udicial use of the equitable doctrine of estoppel cannot grant respondent a money remedy that Congress has not authorized.''); *Am. Hosp. Ass'n* v. *Price,* 867 F.3d 160, 167 (D.C. Cir. 2017) (''[I]f the necessary means [to remedy a legal violation by an agency] were unlawful, the Court could not have mandated them.'').

[20] We continued to enforce retroactively the payment limitations in section 1886(*l*) of the Act (42 U.S.C. 1395ww(*l*)) until Congress stepped in to relieve us of that requirement. *See* CAA 2023, sec. 4143.

threaten Congress' control of the Federal budget.

Adhering to the usual statutory constraints on our rulemaking authority under section 1833(t) of the Act (42 U.S.C. 1395*l*(t)) is particularly appropriate here when we are implementing a remedy through rulemaking rather than adjudication or resolving a matter through settlement. Following judicial interpretations does not necessarily entitle parties without jurisdictionally proper active challenges to have that interpretation applied to prior years' payments. *See* 42 CFR 405.986(b) (change in legal interpretation based on judicial decision not good cause to reopen adjudications); *see also Baptist Mem'l Hosp.* v. *Sebelius,* 603 F.3d 57, 64 (D.C. Cir. 2010) (denying mandamus to party who sought application of favorable judicial interpretation to prior payment years without pending appeals). Parties who chose to sit on the sidelines might benefit *prospectively* from a change in legal interpretation based on a court ruling, but nothing requires an agency affirmatively to reach back and disturb the finality of payment determinations that providers never properly challenged. *See Grant Med. Ctr.* v. *Hargan,* 875 F.3d 701, 707 (D.C. Cir. 2017) (''[W]e *never* require agencies to apply rules retroactively even where it would be permissible for them to do so.'' (emphasis in original)); *see also See Your Home Visiting Nurse Servs., Inc.* v. *Shalala,* 525 U.S. 449, 455 (1999) (holding that ''agency's refusal to reopen a closed case is generally 'committed to agency discretion by law' and therefore exempt from judicial review''); 42 CFR 405.986.

Despite these well-established principles, Congress has recognized that sometimes an agency might decide that finality should yield to other policy considerations, including by giving the agency the flexibility to issue retroactive rules in certain circumstances. *See* section 1871(e) of the Act (42 U.S.C. 1395hh(e)). As we explained in the proposed rule, that threshold has been met here, at least to the extent this rule is retroactive. We add that the same principles that sometimes justify acquiescing to a circuit court outside of that court's jurisdictional bounds also supports our choice to apply the Supreme Court's interpretation of section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)) to parties who lack pending claims for those payment years and thus are outside the bounds of the Supreme Court's judgment. Doing so in this case will help to promote uniform treatment of parties under the law and save the government and regulated parties from uncertainty and litigation costs. We find particularly compelling the fact that we repeatedly stated our view that the preclusion provisions in section 1833(t)(12) of the Act (42 U.S.C. 1395*l*(t)(12)) foreclosed any administrative or judicial review, a position with which the Supreme Court ultimately disagreed. Given the unique circumstances of this case, we believe extending the remedy to the entire industry through rulemaking properly balances the agencies and parties' interest in finality and Congress' control of the Federal budget with uniformity and litigation costs.

Comment. One commenter suggested we view the payment through the lens of monetary damages to make 340B providers whole, suggesting that this is an inevitable consequence of losing a court case.

Response. We appreciate this commenter's transparency in identifying that the make-whole payments that many commenters are requesting are in fact money damages. But we disagree that money damages are appropriate here. Providers sued under section 1869 (42 U.S.C. 1395ff) of the Social Security Act, which authorizes both courts and the agency to ''affirm[], modify[], or revers[e]'' administrative decisions on individual requests for payment under section 205(b) or (g) of the Act (42 U.S.C. 405(b) or (g)). Because the Social Security Act does not authorize money damages, we do not believe that is the correct framework to understand the remedy here. *Cf. Schweiker* v. *Chilicky,* 487 U.S. 412, 424 (1988) (''[T]he [Social Security] Act, however, makes no provision for remedies in money damages against officials responsible for unconstitutional conduct that leads to the wrongful denial of benefits.''). Indeed, even when money damages are appropriate, courts have suggested the goal is to place plaintiffs in the same position as they would have been absent any breach, suggesting the windfall payments for non-drug items and services would need to be deducted from any recovery, regardless. *See Cmty. Health Choice, Inc.* v. *United States,* 970 F.3d 1364, 1375–1376 & n.10 (Fed. Cir. 2020) (''[W]hen the non-breaching party indirectly benefits from the defendant's breach, 'in order to avoid overcompensating the promisee, any savings realized by the plaintiff as a result of the . . . breach . . . must be deducted from the recovery.' '').

After consideration of comments received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing our proposed policy as proposed. In particular, we are finalizing our proposal to make lump sum payments, calculated as the difference between what an affected 340B covered entity hospital received for 340B-acquired drugs during the time period at issue and what they would have received for 340B-acquired drugs if the 340B adjustment had not been in place, as detailed further below. We are doing so for the reasons stated in our proposed rule and in this final rule.

We note that because we are finalizing our proposal to remedy the 340B drug payments through lump sum payments, we must also address the non-drug item and services payment made from CY 2018 through CY 2022 as detailed in subsequent sections of this final rule. We note that because OPPS 340B drug payment is directly and inextricably linked to the OPPS payment for non-drug items and services, if the 340B drug payments are invalidated and must be remedied, then the increased payments for non-drug items and services are invalidated and must be remedied as well. But for the reductions in the 340B drug payments, the increased payments for the non-drug items and services would not have been put into effect.

b. Estimated Reduction in Drug Payments to Affected 340B Covered Entity Hospitals in CY 2018 Through September 27, 2022

An estimated 1,686 340B covered entity hospitals were paid at the 340B payment rate, which was generally ASP minus 22.5 percent for 340B-acquired drugs for CY 2018 through September 27th of 2022, rather than the default rate, which is generally ASP plus 6 percent, due to the 340B Payment Policy. In the proposed rule, CMS estimated that these hospitals received approximately $10.5 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B policy not been implemented. In the proposed rule (88 FR 44084), we stated that we would update these estimated figures in the final rule as we continued to receive updated CY 2022 claims data. In the proposed rule, we expected to have sufficient CY 2022 340B drug claims at issue submitted by September 27, 2023; therefore, by the publication date for the final rule, we estimated we would have sufficient claims data to state with more specificity the reduction in drug payments to affected 340B covered entity hospitals in CY 2018 through September 27, 2022. As discussed in the proposed rule, we estimated that 340B

providers had already received $1.5 billion in remedy payments through reprocessed claims for 340B drugs provided from January 1, 2022, through September 27, 2022. Accordingly, we estimated in the proposed rule that the remaining remedy amount that affected 340B covered entity hospitals had not yet received as a result of this policy was $9.0 billion.[21]

In the proposed rule, we calculated the estimated aggregate payments by isolating 340B drugs assigned status indicator ''K'' (non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals) and billed with modifier ''JG'' (drug or biological acquired with 340B Program discount, reported for informational purposes). We then calculated the difference between these drugs' CY 2018 through 2022 340B payment rate and the 340B rate proposed in the proposed rule, which was generally the difference between ASP minus 22.5 percent and ASP plus 6 percent. We used a similar process to estimate aggregate payments owed for drugs with payment amounts based on WAC or AWP. In particular, for drugs priced using WAC, we calculated the difference between WAC minus 22.5 percent and WAC plus 3 or 6 percent, as applicable; and for drugs priced using AWP, we calculated the difference between 69.46 percent of AWP and 95 percent of AWP. We note that the WAC and AWP based payment rates outlined in this paragraph are the common longstanding default OPPS drug payment rates if ASP data are not available.

We invited comment on this proposed methodology of estimating the reduction in drug payments to affected 340B covered entity hospitals in CY 2018 through September 27, 2022.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

[21] We noted that the additional amount CMS pays affected 340B covered entity hospitals through this remedy could decrease if additional CY 2022 claims are processed at the higher payment rate, as discussed under section I.C of this final rule. As previously explained, the agency complied with the District Court's September 28, 2022, decision by paying the default rate (generally ASP plus 6 percent) for all CY 2022 claims for 340B-acquired drugs paid from September 28, 2022, onward. However, as some affected 340B covered entity hospitals are still filing, or re-filing, claims for CY 2022, we are paying those claims at the higher default payment rate for drugs, which is generally ASP plus 6 percent. Therefore, we advised that our estimate of the total amount of additional drug payments that would be made through this remedy could change as more claims from CY 2022 are processed, or reprocessed, at the default payment rate of ASP plus 6 percent.

Comment: Most commenters generally agreed with our methodology to calculate what 340B covered entity hospitals would have received. Commenters generally requested that we update our calculations for the final rule.

Response: We thank commenters for their support.

As stated in the proposed rule and as requested by commenters, we updated these calculations using claims data available (CMS Common Working File (CWF) CWF2023w38, processed by 09/22/2023) as of the publication of this final rule. Our updated claims data reflects that these hospitals received an estimated $10.6 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B policy not been implemented.

Additionally, we now estimate that $1.6 billion of the total $10.6 billion that we calculated affected 340B covered entity hospitals did not receive as a result of the 340B Payment Policy has already been remedied through reprocessed claims. Accordingly, we estimate the remaining remedy amount that affected 340B covered entity hospitals have not yet received as a result of this policy is $9.004 billion, which has changed from the estimated $9.003 billion amount that was included in the proposed rule. This change is due to additional CY 2022 claims that have been reprocessed as well as an adjustment made based on a comment received as described in section II.B.1.F of this final rule. For simplicity, we refer to this number as $9.0 billion throughout this document.

After consideration of comments received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing our methodology of estimating the reduction in drug payments to affected 340B covered entity hospitals in CY 2018 through September 27, 2022, as proposed. Accordingly, as described in more detail later and in Addendum AAA, we will make total lump sum payments in the amount of $9.004 billion as a result of this final rule. We continue to round our lump sum payment to $9.0 billion for purposes of this final rule discussion for ease of reference, but the exact unrounded amount will be the total amount paid to hospitals.

c. Methodology for Calculating Remedy Payments Owed to Each Affected 340B Covered Entity Hospital

We proposed the following process for calculating the amount of payment owed to each affected 340B covered entity hospital and issuing that payment. For each affected 340B covered entity hospital, we proposed to calculate the amount the hospital would have been paid under the OPPS from CY 2018 through September 27th of CY 2022 for drugs the hospital acquired through the 340B Program had that 340B adjustment not been in effect. We would then subtract from this amount the amount each affected 340B covered entity hospital was paid under the OPPS for 340B-acquired drugs during the period of CY 2018 to September 27th of CY 2022.

When added to the adjusted amount paid under the OPPS from CY 2018 through September 27th of CY 2022 for separately payable drugs acquired under the 340B Program, this proposed additional lump sum payment amount would result in the affected 340B covered entity hospital receiving the default ASP plus 6 percent rate (or WAC plus 3 or 6 percent or 95 percent of AWP, as applicable) for drugs acquired under the 340B Program for CY 2018 through September 27th of CY 2022.

We illustrated the proposed process for calculating and paying an affected 340B covered entity hospital's additional lump sum OPPS payments for 340B drugs furnished from CY 2018 through September 27th of CY 2022 in the following example. We explained that using claims data from CY 2018 through September 27th of CY 2022 for which those claims have been processed and OPPS payments already made, we might calculate that a particular 340B-covered entity hospital would have been paid, for example, an estimated $10 million for 340B drugs had the 340B Payment Policy not been in effect during that time period. Then, based on claims data for the same hospital from the same time period, we might calculate that the hospital was actually paid $7.31 million for 340B drugs from CY 2018 through September 27th of CY 2022. In that circumstance, we explained that the 340B covered entity hospital would receive as a lump sum payment $2.69 million, *i.e.,* the difference between these two amounts. We noted that another way to illustrate our estimate of the total amount an affected 340B covered entity hospital would have been paid had the 340B Payment Policy not been in effect (X) is to use the following formula:

$X = (Y/0.775)*1.06$

Where Y is the total amount received under the 340B policy from CY 2018 to September 27th of CY 2022.

We noted that in the example above, the Y would be $7.31 million. Therefore, ($7.31 million/0.775)*1.06 = $10 million. The lump sum payment would be $10 million minus $7.31 million, which equals $2.69 million. We solicited comment on our proposed calculation methodology for calculating remedy payments owed to each affected 340B covered entity hospital.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: All commenters who addressed the issue supported CMS's proposed methodology for calculating remedy payments. The commenters agreed that the methodology minimizes the administrative burden and complexities of reprocessing claims for hospitals and CMS. In addition, the commenters supported the proposed methodology because the lump sum payment would be an efficient method that could be completed in a shorter timeline than alternatives like an adjustment to prospective payments.

Response: We appreciate commenters' support.

After consideration of comments received, and for the reasons stated in the proposed rule and this final rule, we are finalizing our methodology to calculate the remedy payments owed to each affected 340B covered entity hospital as proposed.

d. Instruction to MACs To Remit Remedy Payments

Consistent with our past practice of remitting payments owed due to litigation, we proposed to make additional payments to each 340B covered entity hospital by issuing instructions (such as a Change Request (CR) or a Technical Direction Letter (TDL)) to the 340B covered entity hospital's Medicare Administrative Contractor (MAC), instructing the MAC to issue a one-time lump sum payment to the hospital in the amount calculated using the above described methodology within a specified timeframe, which we proposed would be within 60 calendar days of the MAC's receipt of the instruction. For instance, in the example above, CMS would issue instructions to the relevant MAC instructing it to issue a payment to the 340B covered entity hospital in the amount of $2.69 million within 60 calendar days of the MAC's receipt of the instructions. (We noted that MACs will continue to follow normal accounting processes for collecting repayment amounts that are the result of provider-specific overpayment obligations, as well as other unique situations such as provider bankruptcy or payment suspension, any of which may impact the provider's net payment amount.) We solicited comment from the public on our proposed approach to remitting remedy payments. We specifically sought comment on the timeframe of 60 calendar days in which we proposed to have the MACs make the proposed lump sum payments. Given the number of one-time lump-sum payments to hospitals, the size of the payments, and the overall complexity of this remedy, we believed 60 calendar days was necessary for the MACs to make these payments accurately and precisely to individual hospitals. We sought comment on this timeframe and if another timeframe, such as 30 calendar days, was supported by rationale from commenters.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: Most commenters supported CMS's proposal for MACs to issue a one-time lump sum payment to affected 340B covered entity hospitals within 60 calendar days of the MAC's receipt of the instruction from CMS to make the payment. Many of these commenters emphasized that MACs should begin processing payments upon receipt of CMS instructions rather than waiting until the end of 60 days to start doing so. These commenters also requested that CMS require MACs to submit weekly updates to CMS on the status of the payments.

Response: We thank these commenters for their support of the 60-calendar day payment timeframe. We agree with commenters that MACs should begin processing payments when they receive our instructions, but no payments may be transmitted before this final rule is effective. *See* 5 U.S.C. 801(a)(3). Additionally, CMS will submit instructions to MACs after the deadline to submit requests for technical corrections under the process detailed in subsequent sections. We also agree that MACs should update us about the status of the payments; however, we will defer to the MACs to make communications to CMS following their standard communication practices.

Comment: A commenter encouraged CMS to clarify with MACs a process to ensure hospitals are paid the full amount provided by CMS without delay, bypassing the normal accounting processes discussed in the proposed rule. This commenter expressed concern that allowing MACs to withhold payment would result in disputes between providers and MACs and unreasonably delay payments due to providers. The commenter recommended that CMS clarify that MACs must pay the amount specified by the agency and not permit MACs to withhold payment.

Response: We share the commenter's concern with providing the lump-sum payments quickly and efficiently. We make these payments under sections 1833(t)(14), 1833(t)(2)(E), and (as applicable) section 1871(e) of the Act (42 U.S.C. 1395*l*(t)(14) and (t)(2)(E) and 42 U.S.C. 1395hh(e)(1)(A)); we do not believe they are somehow different in kind from other Medicare payments made under those authorities in a way that justifies exempting them from MACs' usual procedures. As such, MACs will continue to follow normal accounting processes for collecting repayment amounts that follow from provider-specific overpayment obligations, as well as other unique situations such as provider bankruptcy or payment suspension, any of which may impact the provider's net payment amount.

Comment: Multiple commenters requested that CMS state in the final rule that hospitals receiving a remedy payment will also receive information detailing how that payment was calculated and that the payment notice constitutes a final determination. These commenters additionally requested that CMS state in the final rule that a hospital will not waive any claims or give up any legal rights by accepting a remedy payment. These commenters emphasized that providing this information is especially important because OPPS payments for drugs were based on pricing data that can change over time, including AWP, WAC, and ASP; and these drugs may have an established or decreased ASP today, which could lead to confusion regarding whether CMS's remedy payment is based on the historic AWP/WAC/ASP figure or the current ASP figure.

Response: We refer readers to the previous section titled: *Methodology for Calculating Remedy Payments Owed to Each Affected 340B Covered Entity Hospital* for additional information regarding the methodology we used to calculate the lump sum payments. We reiterate that we calculated the payment amounts to approximate what 340B covered entity hospitals would have received had it not been for the 340B Payment Policy. This means using the ASP (or WAC or AWP) based payment rate that would have been paid at that

time instead of the reduced ASP (or WAC or AWP) based payment as a result of the 340B Payment Policy. The remedial payments established by this final rule are being made instead of making case-by-case decisions through a claim-by-claim process. If the hospital does not submit any information during the time period for technical corrections, then the amounts listed in Addendum AAA are the final payment amounts due to the hospital pursuant to this rule. If, however, a hospital does submit information during the technical correction period, then the final payment will only be determined after CMS addresses the hospital's submission. That determination or decision will be the final payment amount determined pursuant to the methodology in this final rule.

Comment: Three commenters recommended that CMS require the MACs to make payment within 30 calendar days of the MAC's receipt of the instruction to pay. These commenters emphasized that swiftly finalizing and effectuating the remedy is in the best interests of CMS and the 340B hospitals and argued that CMS already has estimated the repayment amounts it will issue and could begin laying the groundwork for making these repayments by coordinating with MACs and providing education to MACs beforehand.

Response: We agree that swiftly finalizing and effectuating the remedy is in the best interests of CMS and the affected 340B covered entity hospitals, and we have engaged in the ''groundwork'' activities mentioned by the commenters (estimating the repayment amounts, considering how to operationalize repaying 340B hospitals, and coordinating with the MACs). However, even having done so, we continue to believe that we should give MACs up to 60 calendar days to process payments to minimize the likelihood of payment error. We agree that MACs should begin processing payments upon receipt of our instructions instead of waiting the full 60 days if possible. We believe this timeframe will allow the MACs to make these lump-sum payments accurately and precisely to individual hospitals. Given the number of payments, the size of the payments, and the overall complexity of this remedy, we believe 60 calendar days is a reasonable payment timeframe.

After consideration of comments received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing our policy to instruct the MACs to remit remedy payments to affected 340B covered entity hospitals as proposed. We will make additional payments to each 340B covered entity hospital by issuing instructions to the 340B covered entity hospital's Medicare Administrative Contractor (MAC) and instructing the MAC to issue a one-time lump sum payment to the hospital in the amount calculated using the above-described methodology within 60 calendar days of the MAC's receipt of the instruction.

e. Accounting for Beneficiary Cost-Sharing

In the proposed rule, we discussed that in most circumstances, beneficiaries would pay in the form of coinsurance approximately 20 percent of any additional 340B drug payments that affected 340B covered entity hospitals would have received, absent the CY 2018 through 2022 340B policy. But, as described above, we proposed to make each remedy payment as a one-time lump sum payment through MAC instructions using a combination of statutory authorities, including, if necessary, our retroactive rulemaking authority under section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)) and our equitable adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)). Because these payments are remedy payments issued through MAC instructions relying in part on our equitable adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)), we explained that these payments would not be 340B drug payments subject to beneficiary copayments. Rather, we stated that these remedy payments are analogous to the type of cost report adjustments under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) that we have previously found do not authorize providers to seek additional beneficiary copayments.[22]

We acknowledged that we have previously suggested that any remedy might affect beneficiary cost-sharing. (*See, for example,* 84 FR 61323.) But we noted that we made that statement in 2019, before the litigation was concluded, and well before we proposed how to structure any remedy and determine how it should impact beneficiary cost sharing many years later. With the benefit of a concrete proposed remedy, we clarified that our proposed lump sum payments for the difference in 340B-acquired drug payments due to the 340B Payment Policy would not affect particular beneficiary cost-sharing responsibilities.

We also explained that in these unique circumstances, it is appropriate to exercise our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) to make adjustments ''as necessary to ensure equitable payments'' and for Medicare to pay the full $9.0 billion difference between what 340B hospitals were paid for 340B-acquired drugs from CY 2018 through September 27, 2022, and what they would have been paid for 340B-acquired drugs absent the 340B Payment Policy during this time period, so that affected 340B covered entity hospitals are paid the amount they would have been paid in full without application of the 340B Payment Policy. While we caveated that statement—it would not necessarily be appropriate to make this kind of adjustment under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) to ensure hospitals receive what they would have been paid from Medicare and beneficiaries absent the 340B Payment Policy every time we make a policy change or lose a lawsuit—we find that such an adjustment is necessary for equitable payments in these unique circumstances in part because of the unprecedented scope of the remedy in terms of the amount of money at issue; the number of services, beneficiaries, and claims affected; and the number of years that have passed between the claims and the remedy.

Accordingly, we concluded that here, where we are remedying prior payments, it would be appropriate to set the remedy payment amount under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) so that affected 340B covered entity hospitals would be paid amounts that approximate what they would have been paid for these

[22] For example, section 3138 of the Affordable Care Act added a new section 1833(t)(18) to the Social Security Act (42 U.S.C. 1395*l*(t)(18), providing for an adjustment under section 1833(t)(2)(E) of the Social Security Act (42 U.S.C. 1395*l*(t)(2)(E) to address higher costs incurred by cancer hospitals. Section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E), in turn, directs the Secretary to establish, ''in a budget neutral manner,'' payment ''adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.'' In response to CMS's proposal to implement this adjustment on a per claim basis through increased APC payments, commenters expressed concern that doing so would increase beneficiary copayments since beneficiary copayment is a percentage of the APC payment. These commenters encouraged CMS to implement the adjustment in a way that did not increase beneficiary copayments. Consequently, CMS determined it was appropriate to make the cancer hospital payment adjustment through the form of an aggregate payment to each cancer hospital determined at cost report settlement, as opposed to an adjustment at the APC level, thereby eliminating the higher copayments for beneficiaries associated with providing the adjustment on a claims basis through increased APC payments. *See* CY 2012 OPPS/ASC final rule, 76 FR 74121, 74204 (2011), for our prior use of our equitable adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E) to adjust cancer hospital payments.

drugs absent the 340B Payment Policy, which includes what affected 340B covered entity hospitals would otherwise have been paid by the beneficiary. Therefore, we proposed that the $9.0 billion payment amount would include $1.8 billion, an amount that is equivalent to what affected 340B covered entity hospitals would have collected from beneficiaries for these 340B-acquired drugs if the 340B Payment Policy had not been in effect.

We emphasized that, if our proposal was finalized, affected 340B covered entity hospitals could not bill beneficiaries for coinsurance on remedy payments—regardless of this adjustment—because we would issue this remedy payment through MAC instructions relying in part on our equitable adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)). We cautioned that CMS would consider appropriate administrative action for providers who nevertheless bill beneficiaries for coinsurance. We solicited comments from the public on our proposed approach to accounting for beneficiary cost sharing.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: Commenters overwhelmingly supported our proposed approach and rationale for accounting for beneficiary cost sharing.

Response: We appreciate commenters' support.

After consideration of comments received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing our policy to account for beneficiary cost sharing as proposed. We will exercise our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) to make adjustments ''as necessary to ensure equitable payments,'' to pay the full $9.0 billion difference, including $1.8 billion, an amount that is approximately equivalent to what affected 340B covered entity hospitals would have collected from beneficiaries for these 340B-acquired drugs if the 340B Payment Policy had not been in effect from CY 2018 through September 27, 2022, so that affected 340B covered entity hospitals are paid the approximate amount they would have been paid in full without application of the 340B Payment Policy.

f. Remedy Payment Amounts

We published the following data file that contained our calculations of the amounts owed under the above-described methodology to each affected 340B covered entity hospital for the proposed rule: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.* We solicited comment from the public on the accuracy of the data in Addendum AAA of the proposed rule, particularly with respect to the estimated amount of remedy payment due to each hospital. This addendum can be found online through the CMS OPPS website.[23]

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: A small number of commenters had concerns regarding the payment amounts, including a request for increased transparency. Some commenters expressed a general concern that some hospitals would receive very large lump sum payments relative to their usual OPPS payments. Similarly, one commenter supported the lump sum calculation methodology but requested that CMS share with participating 340B providers more details about the methodology and a list of their 340B claims on which it was used. Additionally, a couple commenters requested CMS verify their individual payment amounts. Specifically, one commenter indicated that the calculation of the amount owed to them was incorrect. This commenter believes that they were owed more than calculated for CYs 2020 and 2021. Another commenter stated that they were owed nearly $640,000 more than calculated due to claims from CY 2019 that were resubmitted and reprocessed after September 27, 2022, and paid at the ASP minus 22.5 percent rate. This commenter requested that CMS take into account claims that were processed and paid at the lower rate through December 31, 2022.

Response: We appreciate these commenters' concerns and have reviewed the general and specific issues they raised. We also reviewed the payment data for these commenters who stated our calculations were incorrect. As a result of our review, we identified several claims accruing prior to CY 2022 that providers submitted in late CY 2022. Because those claims accrued prior to CY 2022, the MACs correctly processed those claims at the ASP minus 22.5 percent rate; and these claims should be part of the lump-sum payments. We have accordingly adjusted the remedy payment for affected claims. This means that some hospitals will receive slightly higher payments than in the proposed rule, which slightly increases the aggregate lump sum payments we are making from $9.003 in the proposed rule to $9.004 in this final rule. We also note it would be impractical to list the millions of claims used to calculate all of the lump sum payments. For increased transparency, Addendum AAA has been revised to include additional CY 2022 data (please see comment below on this subject). To resolve any lingering concerns by individual providers and provide the opportunity for additional transparency, we are establishing the technical correction process noted later in the rule.

Comment: An additional commenter requested clarification with respect to two of its affiliated hospitals, which were identified on Addendum AAA as eligible for payment but did not participate in the 340B Program during the years in question.

Response: We appreciate the commenter's transparency. Our calculations are based on the information that hospitals originally used when submitting claims with the 340B billing modifier, ''JG.'' These two hospitals used the 340B billing modifier ''JG'' for some claims during the time period in which the 340B Payment Policy was in effect, and so they received reduced payments under the 340B Payment Policy. The overall remedy payments for these entities are small relative to other remedy payments for other hospitals, which suggests they may have erroneously included the ''JG'' modifier when initially submitting claims. We will make remedy payments even to providers who submitted the ''JG'' modifier incorrectly, because they would have received reduced payments under the 340B Payment Policy.

Comment: One commenter stated that providers are unable to accurately verify estimates because the paid through date for claims used by CMS to create the estimates has not been documented and communicated to providers. The commenter requested that CMS disclose the paid through date to providers so that they can verify the accuracy of the calculations. Since the same issue will arise for any final settlement, the commenter additionally requested that CMS document and communicate to providers the paid through date used to arrive at a final settlement and give providers time to accept or refute that amount.

Response: We processed (or, in some cases, reprocessed) any claims paid on or after September 28, 2022, using the default rate (generally ASP plus 6

[23] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

percent). In order to ensure we captured all claims appropriately for this analysis, we included all claims with a Claims Process Date (the date the fiscal intermediary completes processing and releases the institutional claim to the CMS common working file) prior to October 12, 2022, or Date of Service on or before September 27, 2022, in our analysis to determine which claims needed to be remedied while ensuring we excluded those claims that were processed or reprocessed at the higher payment rate (generally ASP plus 6 percent).

Comment: Several commenters requested that CMS add an additional column to Addendum AAA displaying the total amount withheld from each 340B hospital for the period from January 1, 2022, through September 27, 2022, before claims were reprocessed to allow hospitals to calculate and confirm the CY 2022 reprocessed claims amounts. These commenters additionally requested that CMS identify the data sets that it used, as well as the cut-off date for any claims data it used, to calculate the amount of the reprocessed CY 2022 claims, even if those data sets were not publicly available.

Response: We concur with the commenters that additional information regarding the process we used to calculate the remedy payment amounts for CY 2022 would be helpful for providers to calculate their CY 2022 reprocessed claims amounts. Our calculations used data from the CMS Common Working File (CWF) OPPS data, CWF2023w38. We also included two additional columns on Addendum AAA: ''CY 2022 (January 1 to September 27) 340B Drugs Payment Withheld'' and ''CY 2022 (January 1 to December 31) 340B Remedy Payment Already Paid.''

Comment: One commenter, referencing the proposed rule's acknowledgment that the $1.5 billion estimated amount for CY 2022 claims through September 27 might change by the time the final rule is issued, requested that CMS include with the final rule an updated addendum of hospital-specific payments to ensure that all activity since the proposed rule was issued has been accounted for.

Response: We agree. The final rule Addendum AAA has been updated with new hospital-specific payment amounts and accounts for all payment activity that has happened since the proposed rule was issued. Our updated claims data reflects that these hospitals received approximately $10.6 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27, 2022, had the 340B policy not been implemented.

Additionally, our updated analysis estimates that $1.6 billion of the total $10.6 billion that affected 340B covered entity hospitals did not receive as a result of the 340B Payment Policy has already been remedied through reprocessed claims. Accordingly, we estimate the remaining remedy amount that affected 340B covered entity hospitals have not yet received as a result of this policy is $9.004 billion (rounded to $9.0 billion for purposes of discussion in this final rule).

Comment: One commenter requested clarification as to whether the amounts listed in Addendum AAA would be the actual amounts paid, or if those amounts would be subject to sequestration. If subject to sequestration, the commenter requested clarification as to the percentage of the reduction. Another commenter requested that CMS not impose sequestration on the repayments since the sequestration adjustment was suspended during the PHE when most of the payments occurred.

Response: The calculated amounts in Addendum AAA are based on original claims that already included any applicable sequestration. We do not need to apply any additional adjustments for sequestration. The sequestration percentage, when applicable, that applied to the original claim will also apply to the remedy payment because the remedy amount is calculated from the sequestration reduced amount. For instance, if the original claim did not have any sequestration adjustment because the claim was paid during the COVID–19 PHE when the sequestration adjustment was suspended, then remedy payment calculation for that claim would not reflect any sequestration adjustment. The lump sum payments were calculated to provide a payment amount as close as possible to what hospitals would have received if not for the 340B Payment Policy, including any sequestration adjustment that would have applied. The amounts included in Addendum AAA are the amounts that hospitals will receive, except that payment amounts may be affected by MACs continuing to follow normal accounting processes for collecting repayment amounts stemming from provider-specific overpayment obligations, adjustments resulting from errors identified through the lump-sum technical correction process described below, as well as other unique situations such as provider bankruptcy or payment suspension, any of which may impact the provider's net payment amount.

Comment: Many commenters requested a process for affected 340B covered entity hospitals to challenge CMS's calculation of their remedy payment. One commenter requested that CMS provide hospitals with additional time, beyond the 60-day proposed rule comment period, to review the repayment amounts listed in the data file and submit data to CMS justifying an alternative repayment amount. Another commenter suggested that hospitals be provided with 120 days from the date of payment of the lump sum payment to file a dispute, with supporting evidence, that CMS underpaid the hospital for 340B claims for separately payable drugs provided from 2018–2022. One commenter requested that CMS establish a quick, collaborative method for addressing any miscalculation of the remedy payments due. Specifically, the commenter recommended a method with clear, short timelines and a requirement for MACs to respond and resolve any issues quickly.

Response: We agree with commenters that there should be a prompt process for affected 340B covered entity hospitals to request the correction of any errors that hospitals identify in CMS's calculation of the specific remedial payment. Consequently, we are establishing a technical correction process. An affected 340B covered entity hospital can alert CMS to potential errors in the calculation of their lump sum payment amount in Addendum AAA by emailing CMS at the following address, *outpatientpps340b@cms.hhs.gov,* no later than 11:59 p.m. Eastern Standard Time (EST) on November 30, 2023. Submissions must include (1) a description of the nature of the error; (2) a designated contact person for the purposes of addressing the error; and (3) relevant supporting documentation such as claim numbers, total units, payment amount received, date of payment. We will pay the lump sum to an affected 340B covered entity hospital using this process after the alleged calculation error has been reviewed and resolved by CMS. We will work as diligently as possible to resolve any potential technical corrections submitted promptly. Depending on the complexity of the potential technical correction submitted, and the volume of overall technical corrections submitted, processing technical corrections could take us substantial additional time, and hospitals submitting technical

correction requests may be paid after other hospitals.

Comment: Multiple commenters requested that CMS clarify that the final rule does not affect the procedural stature of any open or stayed administrative appeals and that it intends the final rule to be subject to judicial review. These commenters specifically requested that CMS state that reliance on section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) as authority for these adjustments is not intended to create any implication that the adjustments are not subject to judicial review.

Response: Because this rule fully compensates providers for the amounts they claimed they are owed on the 340B payment issue, we believe this action moots any pending appeals on that specific issue. Accordingly, if a provider were to proceed with a pending appeal that would, in effect, be seeking double recovery for the same service. A court's jurisdiction to review all or part of this rule is outside the scope of this rulemaking.

The following updated data file contains the final amounts owed under the previously described finalized methodology to each affected 340B covered entity hospital for the final rule: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

g. Anticipated Timing of Remedy Payments

In the proposed rule (88 FR 44086), we stated that, if we finalized the proposal to pay affected 340B covered entity hospitals in the manner described above, we would propose to make these additional payments at the end of CY 2023 or beginning of CY 2024, after the rule had been finalized and the MAC instructions for each affected 340B covered entity hospital had been issued.

We received the following comments on our proposals.

Comment: Commenters were nearly universally supportive of our proposal to make the remedy payments at the end of CY 2023 or the beginning of 2024.

Response: We appreciate commenters' support.

Comment: One commenter, expressing concern about the financial situation of safety-net and rural hospitals, requested that, prior to CMS finalizing its rule related to the 340B remedy, CMS authorize the MACs to make an initial payment to hospitals that request it in the amount listed in the proposed rule Addendum AAA. Then, in the final rule, the commenter suggests that CMS would instruct the MACs to make an incremental payment to any hospitals that elected to receive funds immediately based on the final rule and any additional claims that were processed through September 27, 2022. In other words, this commenter requests that CMS instruct the MACs to pay hospitals that ask for immediate payment the amount listed in the proposed rule Addendum AAA prior to the effective date of the final rule and then, in the final rule, instruct the MACs to pay any additional amount due based on the final rule Addendum AAA.

Response: While we appreciate the commenter's concerns, we are unable to authorize any payments until this rule and policy is finalized and effective. As stated above, payments will not be made until this rule is effective, which will occur 60 days after the rule is displayed at the Office of the Federal Register. As additionally noted above, to ensure payments are made accurately, there may be an additional delay for hospitals requesting a technical correction.

After consideration of comments received, for the reasons stated in the proposed rule and this final rule, subject to our clarification above and the technical corrections procedure discussed earlier, we are finalizing our proposal to make these additional payments at the end of CY 2023 or beginning of CY 2024. In summary, we intend to issue instructions for hospitals who do not request any correction to MACs as soon as possible after the technical corrections submission deadline has passed. MACs will be instructed to pay providers as soon as possible after the rule is effective, and payments will be made no later than 60 days after the MAC's receipt of the instructions. We will issue instructions to pay hospitals who submit technical correction requests after those requests are resolved.

h. Eligibility of Remedy Payments for Interest

In the proposed rule (88 FR 44086), CMS also considered its authority to pay interest on the remedy payments but concluded that we did not believe we had the authority to do so.

We received the following comments on our proposals.

Comment: Many commenters disagreed that CMS lacks the authority to pay interest on the remedy payments, pointing to various statutes discussed in the following paragraphs. The majority of these commenters relied on section 1833(j) of the Act (42 U.S.C. 1395*l*(j)), which provides that whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under section 1842(b)(3)(B)(ii) of the Act was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments. Instead, these commenters ask us to construe the Supreme Court's decision in *American Hospital Association* as a ''final determination.''

Response: As described here and in the following several responses, we do not agree that any provision identified by commenters provides CMS with authority to pay interest. Commenters do not identify any administrative ''final determination'' that would trigger the interest provision in section 1833(j) of the Act (42 U.S.C. 1395*l*(j)). And our regulations foreclose commenters' suggestion to treat the Supreme Court's decision as a ''final determination.'' Our regulations define ''final determination'' in section 1833(j) of the Act (42 U.S.C. 1395*l*(j)) to mean ''[a] written determination of an underpayment.'' 42 CFR405.378(c)(1)(i)(B). We have previously explained that this definition refers to ''administrative, not judicial, determinations; therefore, there is no interest obligation under these regulations for judicial determinations.'' Medicare Program; Changes Concerning Interest Rates Charged on Overpayments and Underpayments, 56 FR 31332, 31335 (1991).

That interpretation is reinforced by the specific litigation interest provisions in the Medicare statute. Congress provided that cost reports appealed to the Provider Reimbursement Review Board are generally subject to interest beginning 180 days after an intermediary's or the Secretary's final determination. *See* section 1878(f)(2) of the Act (42 U.S.C. 1395oo(f)(2)). And in the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Congress amended the judicial review process for individual appeals and authorized litigation interest only in cases granted expedited judicial review under section 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2). *See* Medicare Prescription Drug, Improvement and Modernization Act of 2003, Public Law 108–173, section 931(a), 117 Stat. 2066, 2399 (2003). By providing interest provisions that apply specifically to judicial determinations, Congress confirmed our reading that section 1833(j) of the Act (42 U.S.C. 1395*l*(j))

applies only to administrative determinations.

Additionally, changing our interpretation of administrative determination may cause the various interest statutes to conflict. For example, if a cost report appeal is denied by an intermediary and a court ultimately finds that payment should have been made, would interest run from 180 days after the intermediary's decision under section 1878(f)(2) of the Act (42 U.S.C. 1395oo(f)(2)), or from 30 days after the court's decision, under commenter's interpretation of section 1833(j)? We decline to construe section 1833(j) of the Act (42 U.S.C. 1395*l*(j)) in a way that could conflict with other provisions of the Act.

We also disagree that the Supreme Court's decision would be a qualifying ''final determination'' under section 1833(j) of the Act (42 U.S.C. 1395*l*(j)), even assuming judicial decisions could sometimes qualify. Interest under this statute runs from a ''final determination'' that the payment made ''was in excess of or less than the amount of payment that is due.'' But the Supreme Court never calculated how much less the plaintiff hospitals were paid than due, declining to consider remedies in the first instance and instead focusing on the purely legal issue of whether the payment rates in the CY 2018 and 2019 OPPS rules exceeded CMS's authority under section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)). *Am. Hosp. Ass'n,* 142 S. Ct. at 1903, 1906. On remand, the district court similarly rejected the plaintiff hospitals' invitation to calculate the amount owed, whether to the parties before the court or to the entire industry. *See Am. Hosp. Ass'n,* 2023 WL 143337, at *3 (declining to issue ''order commanding HHS to repay each underpaid claim to the penny, [because] that cannot possibly be the only rational choice available to the agency''). Because the Supreme Court never determined the amount of underpayment on which interest would run, its decision is not a ''final determination'' of the ''amount'' of underpayment under section 1833(j) of the Act (42 U.S.C. 1395*l*(j)).

Because commenters have not identified a final administrative determination of an underpayment, we do not believe that section 1833(j) of the Act (42 U.S.C. 1395*l*(j)), as construed by 42 CFR 405.378(c)(1), would authorize CMS to pay interest on the proposed remedy payments.

Comment: Two commenters argued that even if CMS is correct that interest is not due on the amount owed to all hospitals that will receive lump sum payments, interest is due to plaintiffs in several cases pending before the United States District Court for the District of Columbia that were stayed pending the outcome of CMS's remedy discussed in the proposed rule. These plaintiffs, the commenters contend, are entitled to prevailing party interest under 42 CFR 405.990(j)(2). These commenters argue that, in appealing CMS's initial determination to pay 340B drug claims at the unlawful rate, these plaintiffs clearly communicated to CMS that the rate of ASP minus 22.5 percent exceeded the Secretary's authority and should instead have been paid at ASP plus 6 percent as required by law. When CMS refused to remit payment of ASP plus 6 percent through these administrative proceedings, the plaintiffs thus sufficiently exhausted the administrative appeals process, giving them standing for judicial review under 42 U.S.C. 405(g), and entitling them to the usual interest awarded to prevailing parties that seek an expedited path to judicial review.

Response: 42 CFR 405.990(j)(2) implements section 1869(b)(2)(C)(iv) of the Act (42 U.S.C. 1395ff(b)(2)(C)(iv)). That provision allows a reviewing court to award interest to a prevailing party in litigation where a provider of services or supplier was granted expedited judicial review pursuant to section 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2)). We are not aware of any providers who received expedited judicial review pursuant to subparagraph (b)(2), and so, even assuming that provision authorizes CMS to pay interest under section 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2)) without a court order, it would not authorize interest payments on the remedy payments here.

To the extent that commenters mean to suggest that section 1869(b)(2)(C)(iv) of the Act (42 U.S.C. 1395ff(b)(2)(C)(iv)) also applies when a court excuses the usual exhaustion requirements contained in section 1869(b)(1) of the Act (42 U.S.C. 1395ff(b)(1)), we disagree. Litigation interest is the exception to cases filed under section 1869, not the rule. No statute authorizes interest for litigants who follow the usual administrative appeal procedures contained in subsection (b)(1). And courts have held that it is subsection (b)(1)'s reference to section 205(g) that authorizes courts to excuse subsection (b)(1)'s exhaustion requirement. *See Tataranowicz* v. *Sullivan,* 959 F.2d 268, 272 (D.C. Cir. 1992). Subsection (b)(2) contains no such reference to section 205(g), and so we doubt the same reasoning would apply. *Cf.* 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2)) (limiting review to the ''civil action described in this subparagraph''). If Congress wanted to extend litigation interest to cases where courts had waived exhaustion under subsection (b)(1), it could have done so when amending that statute to add subsection (b)(2). Because Congress did not, we decline any invitation to extend section 1869(b)(2)(C)(iv) (42 U.S.C. 1395ff(b)(2)(C)(iv) beyond its plain text, especially considering implications litigation interest has on the United States' sovereign immunity and Congress's control of the public fisc. *See, for example, Libr. of Cong.* v. *Shaw,* 478 U.S. 310, 316 (1986) (''For well over a century, this Court, executive agencies, and Congress itself consistently have recognized that federal statutes cannot be read to permit interest to run on a recovery against the United States unless Congress affirmatively mandates that result.'').

Comment: One commenter stated that the Federal Tort Claims Act provides for post-judgment interest (28 U.S.C. 2674) and requested post-judgment interest from June 15, 2022, the date of the Supreme Court's decision, to the date of final payment. Another commenter argued that the remedy payments are subject to the Prompt Payment Act, as amended, and its rules, which state that ''the temporary unavailability of funds does not relieve an agency from the obligation to pay these interest penalties or the additional penalties required under § 1315.11.'' *See* 5 CFR 1315.10(b)(4). This commenter additionally notes that the failure of CMS to make interest payments could result in additional litigation. Similarly, another commenter stated that section 1815(d) of the Act (42 U.S.C. 1395g(d)) and common law provide for the payment of interest on underpayments to Medicare providers.

Response: We do not agree with commenters that the authorities cited would provide CMS the ability to include interest as part of these lump sum remedy payments. No lawsuit has been filed under the Federal Tort Claims Act, and so its interest provisions are irrelevant. *See* 28 U.S.C. 2674 (limiting section to ''the provisions of this title relating to tort claims''). Nor do we believe Medicare providers are subject to the Prompt Payment Act's terms. *Cf.* 5 CFR 1315.1 (limiting applicability to procurement contracts and vendors). Even if they were, that statute does not apply to instances where, as here, ''payment that is not made because of a dispute between the head of an agency and a business concern over the amount of payment.'' 31 U.S.C. 3907(c). Section 1815 of the Act (42 U.S.C. 1395g(d)) governs Part A payments, not Part B, and so is similarly irrelevant. *See* SSA

section 1815(d) (42 U.S.C. 1395g(d)) (limiting applicability to payments ''under this part'').

Comment: A couple commenters directed CMS to the Medicare Claims Processing Manual (100–04, Chapter 1, Section 80.2.2) for instructions for assessing and calculating interest due on non-periodic interim (PIP) claims not paid in a timely manner by fiscal intermediaries and carriers. Another commenter referenced MLN Matters No. MM3557 and argued that the 340B claims were clean and unpaid, therefore, based on CMS regulations, interest should be paid from the date of receipt of the claim. These commenters assert that these claims were not processed in a timely manner, rendering them eligible for interest accrual.

Response: We appreciate commenters highlighting these instructions. Our clean claims regulations are found at 42 CFR 405.922 and implement section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)). Section 1842(c)(2)(B)(i) of the Act (42 U.S.C. 1395u(c)(2)(B)(i)) defines a clean claim as a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part. Section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)) provides that if payment is not issued, mailed, or otherwise transmitted within an applicable number of calendar days after a clean claim is received, interest shall be paid at the rate used for purposes of section 3902(a) of title 31, United States Code for the period beginning on the day after the required payment date and ending on the date on which payment is made. Our longstanding position has been that section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)) does not apply in situations like this one where a payment regulation was properly applied by the contractor to deny a claim that is ultimately held unlawful by a court. No contractor has the authority to ignore CMS's binding regulations and make a payment at odds with the regulations within 30 days or otherwise, and so we believe this is a ''particular circumstance requiring special treatment.'' *Accord* Medicare Program: Changes to the Medicare Claims Appeal Procedures, 74 FR 65296, 65302 (2009) (''Claims initially denied and subsequently paid following a favorable appeal decision, or revised following a reopening action are, by their nature, claims that require special treatment.''). As noted above, the Act speaks expressly to the issue of litigation interest. And reading section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)) to apply to litigation interest raises a similar conflict as reading section 1833(j) of the Act (42 U.S.C. 1395*l*(j) to apply to litigation interest. For example, if a claim denied by a contractor under CMS's regulations was later certified for expedited judicial review under section 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2)), would interest run from 30 days after receipt by the contractor under section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)), or from 60 days after certification under section 1869(b)(2)(C)(iv) of the Act (42 U.S.C. 1395ff(b)(2)(C)(iv))? We decline to construe section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)) in a way that could conflict with other provisions of the Act.

Comment: One commenter requested that CMS share the citations for the authority prohibiting the payment of interest.

Response: As noted above, the Supreme Court has clarified that ''[f]or well over a century, this Court, executive agencies, and Congress itself consistently have recognized that Federal statutes cannot be read to permit interest to run on a recovery against the United States unless Congress affirmatively mandates that result.'' *Libr. of Cong.* v. *Shaw,* 478 U.S. 310, 316 (1986). The proper analysis is thus whether there is legal authority affirmatively mandating the payment of interest here. CMS's inability to pay interest is a consequence of a lack of authority authorizing it to pay interest, not any authority prohibiting it from paying interest.

Comment: One commenter recommended that CMS work with Congress to allow the remedy to include interest.

Response: We appreciate the commenter's recommendation. As noted, a legislative change would require Congressional action.

Comment: One commenter asked if CMS has considered adjusting future budget neutrality provisions to account for the amount of interest reasonably owed 340B providers.

Response: Since we are not adopting a policy to pay interest in this rule, we have not examined whether doing so would require changes to the budget neutrality adjustments discussed below. We agree with the commenter that if we were to pay interest, we would need to evaluate what, if any, impact such interest would have on budget neutrality requirements.

After a consideration of comments received, and for the reasons discussed above, we continue to believe that we do not have the authority to include interest as part of the lump sum payments. We therefore are finalizing our proposal that the lump sum remedy payments would not include interest as proposed.

2. OPPS Non-Drug Item and Service Payments From CY 2018 Through CY 2022

a. Background

As described in the proposed rule, the 340B Payment Policy was implemented in a budget neutral manner under sections 1833(t)(9)(B) and 1833(t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(9)(B) & (t)(14)(H)) by increasing non-drug item and service payments to all OPPS providers for CY 2018 through CY 2022. As we explained in the proposed rule, to comply with the statutory budget neutrality requirements in sections 1833(t)(9)(B) and 1833(t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(9)(B) and (t)(14)(H)), as well as section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)), CMS must account for these additional payments, which were made solely due to the 340B Payment Policy that was in effect from CY 2018 through CY 2022, in determining a remedy for the 340B policy. As described in the proposed rule, after the Supreme Court's decision in *American Hospital Association,* those additional payments became a windfall—payments the hospitals should not have received but did anyway. We noted that to comply with budget neutrality and restore the situation as closely as reasonably possible to the state that would exist if we simply re-ran all the claims from 2018 to 2022 under the correct payment rules, we must recover this windfall.

As summarized in the proposed rule, the reduction in 340B drug payments made to affected 340B covered entity hospitals from CY 2018 through CY 2022 was offset by an increase in non-drug item and service payments made to all hospitals paid under the OPPS during the same time period to comply with statutory budget neutrality requirements. In other words, all hospitals were paid more under the OPPS for non-drug items and services for CY 2018 through CY 2022 than they would have been paid absent the 340B Payment Policy. As we explained, starting in CY 2018, CMS applied an approximate 3.19 percent increase to the OPPS conversion factor to offset the decreased OPPS 340B drug payments. And, as we also explained, because we proposed to make additional payments to affected 340B covered entity hospitals

to pay them what they would have been paid had the 340B policy never been implemented, we were required to correspondingly propose to make an offset to maintain budget neutrality as if the 340B Payment Policy had not been in effect during CY 2018 through CY 2022. As detailed in the proposed rule, this is consistent with the policy finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71976) where CMS finalized a minus 3.09 percent adjustment to the conversion factor as this adjustment removes the effect of the 340B policy as originally adopted in CY 2018, again, as described in more detail in section I.C. of the proposed rule. The CY 2023 adjustment to the conversion factor ensures it is equivalent to the conversion factor that would be in place if the 340B Payment Policy had never been implemented.

As we described in the proposed rule, to calculate the additional amount CMS paid for non-drug items and services, we proposed to include those assigned the following status indicators, SI = J1, J2, P, Q1, Q2, Q3, R, S, T, U, V. These status indicators generally capture the non-drug items and services impacted by a change in the OPPS conversion factor. For additional details on these status indicators, we refer readers to Addenda D1 of the CY 2023 OPPS/ASC final rule with comment period for the most recent OPPS status indicators and their definitions. This file is available on the CMS website.[24] As we noted in the proposed rule, we calculated the adjusted payment (the payment that would have been made for the non-drug item or service absent the budget neutrality adjustment to the conversion factor due to the 340B Payment Policy) by taking the amount paid for the non-drug item or service and dividing it by 1.0319 (the amount by which the conversion factor was increased during CYs 2018 through 2022 to budget neutralize the effect of the 340B Payment Policy). We proposed that the amount that would need to be offset to maintain budget neutrality in crafting this remedy would be based on the payments to providers that would have been made for non-drug items and services absent the 340B Payment Policy during CY 2018 through CY 2022, and the Medicare payment to 340B providers for the amount equivalent to the additional drug payments that would have otherwise been paid as beneficiary cost-sharing. Based on these factors, we proposed prospectively to offset $7.8 billion in order to maintain budget neutrality. This figure was calculated based on past claims data with 80 percent of this amount based on the Medicare share and 20 percent based on the beneficiary share. As we explained, our budget -neutrality adjustment in the 2018 through 2022 OPPS rules reflected a prediction regarding how much we would spend on 340B drugs—a prediction that turned out to be too low. As it turned out, 340B hospitals spent more on 340B drugs than we expected, so our policy ended up saving the Trust Fund (and beneficiaries) more money from cutting the rates paid for 340B drugs than the Trust Fund (and beneficiaries) paid for non-drug services in our budget-neutrality adjustment to offset the savings. We explained that our proposed remedy would achieve budget neutrality by reversing that imbalance. We proposed that in aggregate, the total additional payment that providers would receive as a result of this remedy, $10.5 billion, would be larger than the amount of payment that would be prospectively offset, $7.8 billion. As we explain below and stated in the proposed rule, we believe that our proposed remedy, which would effectively reverse the imbalance that arose under the policy the Supreme Court deemed unlawful and would reasonably approximate the results that would occur if we simply re-ran the claims after eliminating the 340B adjustment, reflects the best approach to budget neutrality in these unique circumstances. We solicited comments from the public on our proposed approach to implementing budget neutrality.

Comment: We received many comments on our proposed approach to implementing budget neutrality.

Response: These comments are addressed in Section II.B.2.b of this final rule.

b. Prospective Adjustment to Payments for Non-Drug Items and Services To Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022

As described in the proposed rule (88 FR 44087), we believe that sections 1833(t)(2)(E) and (t)(14) of the Act (42 U.S.C. 1395*l*(t)(2)(E) and (t)(14)) are properly read to require budget neutrality. As we explained in the proposed rule, section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) provides that adjustments under that provision must be made in a budget neutral manner. Section 1833(t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(14)(H)) states that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years, while section 1833(t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(9)(B)) states that the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. To implement these requirements, we proposed to unwind the additional payments that were made for non-drug items and services to all providers from CY 2018 through CY 2022. In other words, along with reversing the rate change we discussed in the proposed rule, we proposed to reverse the accompanying increase in the conversion factor for CYs 2018 through 2022 that was solely attributable to the adoption of the 340B Payment Policy.

As described in the proposed rule, to reduce the burden on providers of offsetting the $7.8 billion offset required to maintain budget neutrality, we proposed to implement the adjustment prospectively. We proposed to, beginning in CY 2025, reduce all payments for non-drug items and services to all OPPS providers—except any hospital that enrolled in Medicare after January 1, 2018—by 0.5 percent each year until the total offset was reached (which we estimated to be approximately 16 years). As stated in the proposed rule, starting this reduction in CY 2025 would allow CMS time to finalize its methodology, and then apply its methodology to calculate and publish the payment rates in the CY 2025 OPPS/ASC proposed rule. We stated it would also allow adequate time for impacted parties to assess and prepare for the new payment rates that would be calculated using a reduced conversion factor. Additionally, as we remarked in the proposed rule, we believed a 0.5 percent annual reduction in the conversion factor would be appropriate because it would balance the need to address the past payments for non-drug items and services to ensure budget neutrality while also ensuring that the offset was not immediately, in the short-term, overly financially burdensome on impacted entities, especially those in rural communities, which we believed would be the case if we were to apply an adjustment for the full offset amount in a single year.

In the proposed rule, we acknowledged that, in litigation, we at

[24] *https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1772-fc.*

one point questioned the American Hospital Association's suggestion that we could achieve budget neutrality by decreasing Medicare payments in future years, noting that section 1833(t)(9) of the Act (42 U.S.C. 1395*l*(t)(9)) requires budget neutrality for a particular ''year.'' *See Am. Hosp. Ass'n* v. *Becerra,* Br. for the Respondents, at 30 (U.S. No. 20–1114).[25] At the same time, however, the government's briefing pointed to the District Court's conclusion that if the Secretary was to retroactively increase the 2018 and 2019 payments for 340B hospitals, ''budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services.'' *Ibid.* In the proposed rule, we indicated that we had further considered section 1833(t)(9) of the Act (42 U.S.C. 1395*l*(t)(9)) in light of the Supreme Court's decision holding that judicial review was available and also recognizing the statutory requirement of budget neutrality, and that consequently different ways of approaching the remedy had come into focus.

As we explained in the proposed rule, our proposal was consistent with section 1833(t)(9) of the Act: It would offset the amounts of money that constitute excess payments in past years—which are effectively overpayments for those years (that is, 2018 to 2022) in light of the Supreme Court's decision. In other words, while we proposed reducing the conversion factor in future years, we would be doing so not by seeking to budget neutralize payments across a period of years rather than in a particular ''year,'' but instead by adjusting payment rates for each year from 2018 to 2022 to account for the Supreme Court's decision. We proposed that we would then make the requisite additional payments to 340B hospitals for those years and collect the excess payments from other hospitals in future years. We also explained that because the estimated amount of expenditures for each of 2018 to 2022 would still be budget neutralized—indeed, we stated that it was our best effort to implement the policy that would have been in effect had the 340B policy never been implemented in the first place—we believed it would be consistent with the provision that adjustments may not ''cause the estimated amount of expenditures under this part for the year to increase or decrease.'' *See* section 1833(t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(9)(B)). As noted in the proposed rule, we believed that this interpretation would account for reliance interests hospitals may have in payments already made while staying consistent with the budget neutrality requirements repeated throughout the OPPS statute in sections 1833(t)(2)(E), (t)(9), and (t)(14)(H) (42 U.S.C. 1395*l*(t)(2)(E), (t)(9) and (t)(14)(H)). And, as discussed in the proposed rule, we concluded that avoiding a windfall to providers was consistent with the agency's recoupment authority. We invited comments on these aspects of our proposal.

We also acknowledged that under our proposal the Part B Trust Fund would pay out more for remedial payments than it would recover over time based on the reduction in payments for non-drug items and services. As we explained, that is a consequence of many factors. The most significant factor is our estimate in the CY 2018 OPPS/ASC final rule of the amount that expenditures for 340B-acquired drugs would decrease under the 340B Payment Policy. As part of the 340B Payment Policy, we budget neutralized the decreased payments for 340B-acquired drugs by applying a 3.19 percent adjustment to the conversion factor to increase expenditures for non-drug items and services. In the proposed rule, we acknowledged that Medicare could not perfectly have calculated a precise estimate when it first made the budget neutrality adjustment in the CY 2018 final rule with comment period. In the CY 2018 final rule with comment period, we discussed that, because data on drugs that are purchased with a 340B discount are not publicly available, it was not possible to estimate more accurately the amount of the aggregate payment reduction. That imprecision impacted the budget neutrality adjustment we calculated. We discussed that other potential offsetting factors included possible changes in provider behavior and overall market changes that may have lowered the impact of the payment reduction in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52623).

We now know that CMS underestimated the growth in expenditures for 340B drugs in CYs 2018 through 2022. Therefore, as we stated in the proposed rule, our budget neutrality calculations for those years ended up increasing payments for non-drug services by less than we decreased payments for 340B drugs. As we explained, we followed our standard approach not to propose to re-calculate what the budget neutrality offset would have been beginning in 2018 if we had used more accurate assumptions. Rather, we proposed simply to unwind the 3.19 percent budget neutrality adjustment we set beginning in 2018. Because of our flawed assumptions in 2018, however, the total amount of our proposed remedy payments to 340B hospitals for 340B drugs would thus be greater than the future reduction to payments.

As we explained in the proposed rule, there were other reasons for the difference between the lump-sum payment and our future reductions to non-drug spending. Some of these reasons increase that gap; others do the opposite. First, a large portion of the CY 2022 340B drug claims for dates of service between January 1, 2022, and September 27, 2022, have already been remedied as a result of being processed or reprocessed at the default drug payment rate. However, none of the non-drug item and service claims from CY 2022 have been offset yet to account for our proposed method of budget neutralization. Second, during CY 2022 CMS began making payment for 340B drugs at the default drug payment rate, generally ASP plus 6 percent, for claims processed on or after September 28, 2022; however, no adjustment was made for the increased payment of the non-drug item and service claims that were processed during this time. Therefore, as we explained, there was over an entire quarter of claims for non-drug items and services that were paid a higher rate due to the 340B Payment Policy that still needed to be offset, while the 340B drug claims for that quarter had already been paid correctly.

Additionally, as we remarked in the proposed rule, our proposal included in the remedy payments the amount that affected 340B covered entity hospitals would otherwise have been paid by beneficiaries. This, we explained, would approximate what the hospitals would have been paid for these drugs absent the 340B Payment Policy. Because the statute requires that this adjustment be budget neutral, we proposed to include in the prospective offset calculation an amount to offset this increase in Medicare payments.

In sum, we proposed in the proposed rule a total prospective offset of $7.8 billion to maintain budget neutrality as if the 340B Payment Policy had never been in effect and therefore had never adjusted the OPPS conversion factor. That offset encompasses both the windfall providers received from the Medicare Trust Fund for non-drug services between 2018 and 2022, as well as the additional copayments they received from beneficiaries on those services. And we proposed to use it to offset both the payments we are making

[25] *https://www.supremecourt.gov/DocketPDF/20/20-1114/197027/20211020212647625_20-1114bsUnitedStates.pdf.*

to compensate 340B hospitals for the lower amounts Medicare paid them and the equitable adjustment we are making to compensate for the additional beneficiary copayments they would have received.

To avoid potentially overburdening providers with an immediate downward adjustment to the OPPS conversion factor, we proposed to decrease future payments for every non-drug item and service for every hospital. As we explained, this approach was similar to the original budget neutrality adjustment in the 340B Payment Policy that increased the payment for every non-drug item and service for CY 2018 through CY 2022 to offset the downward adjustment in the payment rate for drugs acquired under the 340B Program. We acknowledged in the proposed rule that, depending on how a hospital's future mix of drug and non-drug services compared to its past mix of drug and non-drug services, as well as any absolute growth in a hospital's non-drug services, some hospitals might ultimately receive slightly more (or less) of a payment reduction than the payment increase they received in CY 2018 through CY 2022. We additionally acknowledged that there is often some imprecision inherent in budget neutrality calculations, and being more precise would require that we recalculate the additional amount that each hospital received under the prior policy and then apply a specific reduction to that hospital's future non-drug service payment rates to offset that amount. As we explained, that alternative was very similar to the claims reprocessing alternative that we discussed in section II.A.2 of the proposed rule, which would impose significant burdens and payment delays for 340B providers. We also explained that because it would be administratively unworkable to tailor individual payment reductions for each of the thousands of impacted hospitals for over a decade and a half, meaning we would likely need to collect a lump sum budget neutrality recoupment. We noted that it would impose all the burdens of an up-front budget neutrality recoupment that we decided against proposing, as explained in section II.A.3 of the proposed rule. We indicated that, except in the case of truly new hospitals, which we proposed to exclude from the prospective offset described under section II.B.2.c of the proposed rule, we did not believe our proposed approach would so significantly undercompensate hospitals to require that kind of precision, despite these potential distributional consequences. *See Shands Jacksonville Med. Ctr., Inc.* v. *Azar,* 959 F.3d 1113, 1120 (D.C. Cir. 2020) (rejecting challenge to remedy rule even when it left some hospitals ''slightly better off and others slightly worse off than they would have been had the rate reduction never taken effect''). Rather, we explained that we believed that our remedy would come as close as reasonably possible to turning back the clock to restore us to the place in which we would have been absent the policy the Supreme Court held unlawful. As we emphasized in the proposed rule, this remedy applies in truly unique circumstances: we must apply budget neutrality in a way that may not be purely prospective, but may be partially retroactive to rectify an adjudicated past violation of law. As discussed in the proposed rule, re-running all the relevant claims as if the 340B Payment Policy did not occur would be close to impossible administratively. Consequently, given these unique circumstances, we explained that we believed our proposed approach properly applied the budget neutrality principle, even if it resulted in some effectively unavoidable imprecision.

Accordingly, as described in the proposed rule, beginning in CY 2025, we proposed to reduce OPPS payments for non-drug items and services annually by decreasing the OPPS conversion factor by 0.5 percent each year until the total offset, estimated to be $7.8 billion in the proposed rule, was reached. We explained that we recognized that the proposed rule was unique and therefore required a unique prospective offset period. We also explained that we believed an annual reduction of 0.5 percent would offset this amount in a reasonable amount of time while not imposing too significant of a reduction on hospitals in any particular year. At the time of the proposed rule, we estimated that this process would take approximately 16 years (Table 1). As detailed in the proposed rule, this estimate was based on current OPPS payments that were made through the OPPS conversion factor and typical year-over-year increases in OPPS payments over the past ten years. We noted that, similar to the original 340B budget neutrality adjustment to the conversion factor, both Medicare payments under the OPPS and beneficiary cost-sharing would be impacted by the change in the conversion factor. As described in the proposed rule, in this instance, beneficiaries would generally have lower co-insurance payments for non-drug items and services as a result of the proposed 0.5 percent annual reduction to the OPPS conversion factor for the duration of the required budget neutrality offset.

We invited comment on our estimated budget neutrality offset calculations described in the proposed rule, including the discussion of our method of budget neutralization not fully aligning with the money we predicted the Part B Trust Fund would pay out in lump sum payments for 340B-acquired drugs. In the proposed rule, we stated that we would adjust this estimate in future CY annual OPPS rules after CY 2025, based on updated data, such as claims and aggregate OPPS spending estimates, to account for how much of the total additional non-drug item and service payment amount had been offset by the time of each annual rule. In the proposed rule, we stated that in the final CY rulemaking for this process, when we estimated the remaining amount of Medicare payment that would needed to be offset fully within the prospective year, the 0.5 percent reduction amount would be reduced in the final year in which the adjustment applied, if needed, to the percentage estimated to be sufficient to offset the remaining amount by the end of that calendar year. After this final prospective adjustment was made, we proposed that we would not make any additional adjustments to the OPPS conversion factor for purposes of offsetting the additional Medicare payments made to remedy the OPPS 340B Payment Policy, nor would we make any additional future adjustments if the amount of the offset in the final year of this adjustment was more or less than we had estimated in rulemaking for that CY. We proposed to codify the 0.5 percent reduction in the OPPS conversion factor effective for CY 2025 in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32.

BILLING CODE 4120–01–P

TABLE 1: ILLUSTRATION OF THE PROPOSED 0.5 PERCENT CONVERSION FACTOR ADJUSTMENT TO THE OPPS NON-DRUG ITEMS AND SERVICES BEGINNING CY 2025 TO MAINTAIN BUDGET NEUTRALITY

	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	$63,724	$66,910	$70,256	$73,769	$77,457	$81,330
0.5-Percent Payment Reduction Amount (millions)	$0	$335	$351	$369	$387	$407
Estimated Total Cumulative Offset (millions)	$0	$335	$686	$1,055	$1,442	$1,849

	CY 2030	CY 2031	CY 2032	CY 2033	CY 2034	CY 2035
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	$85,369	$89,667	$94,150	$98,858	$103,801	$108,991
0.5-Percent Payment Reduction Amount (millions)	$427	$448	$471	$494	$519	$545
Estimated Total Cumulative Offset (millions)	$2,276	$2,724	$3,195	$3,689	$4,208	$4,753

	CY 2036	CY 2037	CY 2038	CY 2039	CY 2040
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	$114,440	$120,162	$126,170	$132,479	$139,102
0.5-Percent Payment Reduction Amount (millions)	$572	$601	$631	$662	$581*
Estimated Total Cumulative Offset (millions)	$5,325	$5,926	$6,557	$7,219	$7,800

**Note, the final year's offset is estimated to be less than 0.5 percent in order to meet the total estimated offset of $7.8 billion.*

We also note the Total Applicable OPPS Non-Drug Item and Service Spending are estimates based on an assumption of 5 percent annual growth. The 5 percent annual growth is determined from a 10-year baseline percentage increase.

BILLING CODE 4120–01–C

We sought comments on the annual percent reduction method described in the proposed rule and whether an alternative option—including those discussed in section II.A of the proposed rule—would be appropriate. We suggested that an additional possible alternative timeline for maintaining budget neutrality could be to offset a fixed dollar amount each year over a fixed period of time such as 5, 10, or 15 years. By way of an example, we suggested that we could divide the $7.8 billion number by 10 in order to offset $780 million per year from CY 2025 through CY 2034 by making an adjustment to the conversion factor to reflect an estimated $780 million reduction in non-drug item and service spending for each year.

As described in the proposed rule, we also considered whether hospitals needed additional time to prepare following any finalized policy, and, as

such, sought comment on whether delaying the proposed reduction in the conversation factor from CY 2025 to CY 2026 would provide hospitals with additional time to make necessary arrangements.

We received the following comments on our proposals.

Comment: Many commenters argued that since, in their view, sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(14) and (t)(2)(E)) do not apply to the remedy payments (for the reasons described under section II.B.1), the budget neutrality requirements of those statutes also do not apply to the remedy payments.

Response: We explain at length above why sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(14) and (t)(2)(E)) are the proper authorities to make these remedy payments. We therefore disagree with commenters that budget neutrality requirements in those provisions would not also apply. And even if a budget neutrality adjustment is not statutorily required, it is an appropriate exercise of the agency's statutory and common-law or inherent recoupment authorities as a policy matter, as we explain further later in this section.

Comment: Some commenters argued that section 1833(t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(14)(H)) cannot authorize our unwinding of the non-drug item and service payments from the 340B Payment Policy. That provision reads, as relevant: ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.'' In their view, there is nothing ''additional'' about the lump sum payment, because it is what 340B hospitals should have been paid in the first place. And the payment is not being made ''as a result of this paragraph'' but rather the agency's loss of a court case. These commenters further disagreed with our reading of section 1833(t)(14)'s reference to paragraph (9), which directs CMS to adjust the groups, relative payment weights, and wage indices in the OPPS ''for a year.'' These commenters argued that this provision is prospective in nature and therefore cannot be relied upon to require or authorize what they characterize as a corresponding retrospective recoupment from hospitals. One commenter interpreted ''additional expenditures'' in section 1833(t)(14)(H) of the Act (42 U.S.C. 1395*l*(t)(14)(H)) to refer only to expenditures from CMS electing to refine its drug payment methodology as permitted under section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)). The commenter asserted that this means performing a survey and changing the drug payment methodology or refining the overhead cost payment, and that, in this case, the additional expenditures are neither of these and are instead ''a loss at the Supreme Court, not a payment methodology refinement.''

Response: We disagree with commenters' interpretation of sections 1833(t)(14)(H) and (t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(14)(H) & (t)(9)(B)). As an initial matter, commenters overlook that we are not adjusting future payments by the $9 billion lump sum payment or by the $10.5 billion total cost of this remedy rule. Rather, we are unwinding the payment increases for non-drug services and items in the 340B Payment Policy (82 FR 59482) in order to place providers in as close to a situation as they would have been if the 340B Payment Policy never existed.

Additionally, the Supreme Court stated it would ''not address potential remedies.'' *Am. Hosp. Ass'n,* 142 S. Ct. at 1903. We are using section 1833(t)(14) of the Act (and sections 1871(e) and 1833(t)(2)(E) of the Act, as relevant) to unwind the 340B Payment Policy. Any increased expenditures are therefore a result of paragraph (14). Section 1833(t)(14) of the Act (42 U.S.C. 1395*l*(t)(14)) does not contain an exception to the budget neutrality requirement when unwinding the agency's past interpretations. Ultimately, we are responding to the Supreme Court's decision for CY 2018 through CY 2022 the same way as we responded to the Supreme Court's decision in the CY 2023 OPPS final rule: unwinding both the payment decrease for 340B-acquired drugs and the payment increase for non-drug items and services. No one objected to the 3.09 percent decrease to payments for non-drug items and services, despite it responding to the same Supreme Court decision and restoring payments for 340B-acquired drugs to what they should have been all along. We believe our approach here is analogous.

We also disagree that the reference in section 1833(t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(9)(B)) to adjustments ''for a year'' diminishes our ability to return providers to the situation they would have been absent the 340B Remedy Policy. We previously explained that the OPPS's generally prospective nature does not prevent us from remedying legal errors identified by courts. We believe we should apply section 1833(t)(9)(B) consistent with that instruction; if a court decision invalidates a policy that impacts payments ''for a'' particular past ''year,'' we can account under section 1833(t)(9) for the impact the legally correct policy would have had for that same year. That is especially true when, as here, the cut to 340B-acquired drugs was so inextricably intertwined with the 3.19 percent increase to payments for non-drug items and services budget neutralized. Because we are making adjustments to payments for CY 2018 through CY 2022, section 1833(t)(9)(B) of the Act (42 U.S.C. 1395*l*(t)(9)(B)) requires us to make corresponding budget neutralizing adjustments to the ''estimated amount of expenditures'' for each of those years. To the extent necessary, this final rule can be viewed as a retroactive adjustment to the payment rates for each of 2018 through 2022, as authorized by section 1871(e)(1)(A) of the Act ((42 U.S.C. 1395hh(e)(1)(A)). We could have, for example, increased the payment rate for 340B-acquired drugs for CY 2018, and decreased the payment rate for non-drug items and services by 3.09 percent for CY 2018 and reprocessed all affected claims. While that solution was not generally supported by the commenters for different reasons, all payment adjustments would have been made in the same year. The fact that we are accomplishing nearly the same result (that is, unwinding the payment decreases and increases for 2018–2022) through the reconciliation process described above and implementing the proper payment or offset amounts does not, in our view, relieve us of the budget neutrality requirements in the statute nor does it render our proposed remedy unreasonable or unsupported by the statutory scheme as a whole.

Comment: One commenter posited that the proposed offsets are not budget neutral because there is no ''budget'' for the period spanning from 2018 to 2041.

Response: The term ''budget neutrality'' is a term of art and does not reference a particular ''budget.'' And even if the term ''budget'' should be construed separately from the rest of the term, a budget does not necessarily have to apply to a defined time frame. *See* BUDGET, Black's Law Dictionary (11th Ed. 2019) (''A sum of money allocated to a particular purpose or project.''). Here, we understand budget neutrality in section 1833(t)(2)(E) (and, to the extent relevant, the title of section 1833(t)(9)(B)) generally to refer to the impact of our policies on OPPS and the Part B Trust Fund—not to any particular written document.

Comment: Some commenters argue that section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E) similarly cannot be used to unwind the payment increases

for non-drug payments and services, both because the provision is prospective in nature and because its reference to ''equitable payments'' refers to ''payments,'' not recoupments or reductions. They argue the surrounding statutory language supports this payment-only reading, as ''outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6)'' should be read to refer to ''additional payment[s],'' not funding that CMS seeks to recoup from hospitals.

Response: We addressed above why we believe OPPS's prospective nature does not make it inapplicable to this remedy rule. Just as section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) is broad enough to encompass individual payments for cancer hospitals (76 FR 74204), it is broad enough to encompass the adjustments to future payments for non-drug items and services we finalize here. Indeed, adjusting future payment years to ensure providers are paid fairly falls comfortably inside the plain text of section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)). We disagree with commenters that the term ''equitable payments'' can never include reductions. The statute authorizes ''adjustments to ensure equitable payments''—not just *upward* adjustments to ensure equitable payments. Similarly, we disagree with the assertion that ''equitable payments'' excludes adjustments to recoup money that should not have been paid; as explained above, restoring parties to the situation they should have been is equitable in every sense of the term.

Comment: A few commenters argued that the retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)) (or anywhere else) does not authorize budget neutrality. One commenter argued that CMS only discussed its retroactive rulemaking authority in the proposed rule with respect to the authority to make the remedy payments, not to budget neutralize the remedy payments. The commenter argues that this is for good reason because CMS cannot rely upon any general retroactive rulemaking statutes to implement an offset because it would rely upon paragraph (9) which is prospective only.[26] Another commenter referenced ''. . . the risk that HHS may lack authority to recoup these funds at all because of the presumption against retroactive rulemaking,'' quoting the district court's remand decision. *See Am. Hosp. Ass'n,* 2023 WL 143337, at *5.

Response: We disagree that our retroactive rulemaking authority would not encompass budget neutrality adjustments. To the extent our proposed rule could be construed to disclaim reliance on section 1871(e)'s retroactive rulemaking authority to our budget neutrality adjustment, we clarify here that we intend to rely on that authority to the extent our budget neutrality adjustment is retroactive.

We read the quoted statement from the district court in *American Hospital Association* simply to acknowledge that the plaintiffs argued that CMS lacked retroactive rulemaking authority. That court did not resolve the question one way or another. By contrast, when Congress passed section 1871(e) of the Act (42 U.S.C. 1395hh(e)), it expressly acknowledged the general presumption against retroactive rulemaking, suggesting it intended to depart from that general rule. *See* H.R. Rep. 108–391 at 756.[27] And when it did so, Congress had already instructed CMS to set up many prospective payment systems, including OPPS. We believe we should harmonize section 1833(t)(9) of the Act (42 U.S.C. 1395*l*(t)(9)) and the other prospective payment statutes with section 1871(e) of the Act (42 U.S.C. 1395hh(e)), not read them to conflict. Such a reading would also be inconsistent with courts' holding that the fact that section 1833(t) of Act (42 U.S.C. 1395*l*(t)) sets up a general prospective system does not mean it implicitly precludes retrospective review.

Comment: Two commenters argued that budget neutrality does not apply to the payments made to plaintiffs in several cases pending before the U.S. District Court for the District of Columbia that were stayed pending the outcome of CMS's remedy discussed in the proposed rule. According to these commenters, these plaintiffs' entitlement to remedial payments is based on judicial review of their individual 340B drug claims under section 205(g) of the Act (42 U.S.C. 405(g)), and therefore the plaintiffs do not rely on associational standing or seek relief that would apply to a broad class of members, which CMS argues implicates budget neutrality. These commenters argue that the plaintiffs' challenge to CMS's 340B Payment Policy under section 205(g) of the Act (42 U.S.C. 405(g)) in no way implicates the budget neutrality provisions referenced by CMS in the proposed rule and that CMS must recognize that the plaintiffs have preserved their rights to seek relief under section 205(g). In their view, section 205(g) provides a process for all hospitals to pursue relief of their own underpaid claims and does not impose or require a single ''one size fits all'' remedy or require budget neutrality recoupment on favorable payment decisions under that process. For this narrow class of hospitals, the commenters maintain, the appropriate remedy is to make the hospitals whole in the same manner that would otherwise occur when the claims are decided favorably through the administrative claims appeals process—that is, without a budget neutrality recoupment.

Response: We agree with commenters to the extent they question whether the associational standing doctrine on which some plaintiffs relied can override the presentment requirements in section 205(g) of the Act (42 U.S.C. 405(g)), authorize the type of individualized payment recalculations addressed in this rulemaking, or otherwise allow industry groups to serve as a class representative for their members without complying with the applicable Federal Rules of Civil Procedure. *See Warth* v. *Seldin,* 422 U.S. 490, 515–16 (1975) (noting associational standing most appropriate for prospective relief and not available for individualized monetary calculations). But we do not believe that difference requires us to treat hospitals with pending cases differently from those without pending cases for the budget neutrality adjustment finalized in this rulemaking.

''One of the earliest principles developed in American administrative law was the idea that 'the choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency.' '' *Almy* v. *Sebelius,* 679 F.3d 297, 303 (4th Cir. 2012) (quoting *Sec. & Exch. Comm'n* v. *Chenery Corp.,* 332 U.S. 194, 203 (1947)). We do not believe that by prescribing an adjudication process in sections 205(b) and (g) of the Act (as incorporated by section 1869), the statute impliedly prohibits us from also addressing through rulemaking interpretative concerns identified by courts or insulates those with pending adjudications from the effects of such rulemaking. Nor do those provisions necessarily exempt pending adjudications from other statutory requirements, such as budget neutrality.

Comment: Many commenters disagreed that, even if budget neutrality was not statutorily required, CMS could

[26] See Reply In Support Of Plaintiffs' Motion to Hold Unlawful And Remedy Defendants' Past Underpayment of 340b Drugs, *Am. Hospital Ass'n* v. *Becerra,* Case No. 1:18–cv–2084, Dkt. 78 at 14–17 (Sep. 21, 2022).

[27] *https://www.congress.gov/108/crpt/hrpt391/CRPT-108hrpt391.pdf.*

still exercise its authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) and its longstanding inherent and common-law recoupment authority to offset the extra payments. These commenters reiterated that section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(e)) does not authorize CMS to make the lump sum payments and, therefore, the budget neutrality requirements of (t)(2)(E) do not apply to the lump sum payments. These commenters also assert that CMS does not have a common-law duty to seek recoupment, so any reliance on common-law would be voluntary, and no common law power of recoupment authorizes the type of recoupment proposed by CMS. They assert that any common-law authority that the government may have to recoup funds can only be exercised by suing in court.

Response: We respectfully disagree with these commenters. As we have explained, we believe a budget neutrality adjustment is statutorily required and, even if not statutorily required, an appropriate exercise of the agency's statutory and common-law or inherent recoupment authorities as a policy matter. As we explain elsewhere in the rule, we believe it falls within our authority to make adjustments ''necessary to ensure equitable payments'' under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(2)(E)) to account for and place hospitals in nearly the same position as they would have been absent the 340B Payment Policy. With respect to commenters' assertion that CMS lacks a common-law duty to seek recoupment, we clarify that we would pursue recoupment even if we were not strictly required to do so by common law; the common law reflects the judgment that the government should avoid funding windfalls to private parties. We agree with that judgment. Finally, courts have not limited the government's authority to recoup funds only to lawsuits; courts have acknowledged that agencies may recoup funds through use of a setoff. *See, for example, Mount Sinai Hosp. of Gr. Miami,* v. *Weinberger,* 517 F.2d 329, 337 (5th Cir. 1975) (''In some circumstances when government funds are improperly paid out the government has a claim enforceable either by direct suit or by setoff against money owed by the government to the recipient of the illegally dispensed funds.'' (footnotes omitted)).

Comment: Many of these same commenters disagreed with CMS's reasoning that applying budget neutrality was justified as sound public policy because the payments constitute an unwarranted windfall to hospitals that the Trust Fund has a strong interest in recovering and that hospitals have no legitimate reliance interest in retaining. These commenters argued that it was inappropriate for CMS to characterize the receipt of these funds as a ''windfall'' since hospitals had no choice but to accept the funds. Commenters additionally objected to CMS's use of the term because it implies that CMS is taking no responsibility for its own role in creating the situation resulting in the payment of the funds that it is now proposing to recoup. These commenters also argued that the proposed rule's reference to any interest that the Trust Fund may have in recoupment is overstated because, based on the most recent Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds, there is no risk that the SMI Trust Fund will become insolvent in the foreseeable future. These commenters disagreed with CMS's contention that achieving budget neutrality serves an important interest in protecting the public fisc. These commenters argued that applying budget neutrality principles increases risks for the public fisc because CMS knows that it can take ''aggressive or unsupported positions at the outset'' and then simply recoup funds later to make up for any mistakes. Finally, these commenters also disagreed with CMS's contention that hospitals have no legitimate reliance interest in permanently retaining the funds proposed to be recouped. Many of these commenters stated that hospitals properly relied on and have already spent the payments CMS made between 2018 and 2022 and that this reliance was particularly pronounced given the COVID–19 PHE.

One commenter opined that, to the extent CMS concludes that it is unreasonable to burden the Trust Fund, and given a lack of authority for a budget neutrality adjustment or retroactive rulemaking, CMS can reasonably conclude that it has no available funds (nor specific appropriation) for the remedy payment, and therefore, the U.S. Treasury Department's Judgment Fund, 31 U.S.C. 1304, could be the appropriate vehicle for satisfaction of providers' claims in this case.

Response: While we appreciate the commenter's suggested alternative for funding the remedy payments, we disagree that we lack the authority to make the lump-sum payments, budget neutralize the remedy, or engage in retroactive rulemaking for the reasons stated earlier in this rule. We continue to believe a budget neutrality adjustment is statutorily required and, even if not statutorily required, an appropriate exercise of the agency's statutory and common-law or inherent recoupment authorities as a policy matter. We also disagree that our approach would encourage aggressive statutory interpretations by the agency or otherwise threaten the public fisc. We of course intend to discharge faithfully our obligation to interpret statutes as best we understand them, and the resources the agency has expended litigating and then unwinding the 340B Payment Policy is itself a significant incentive against departing from that intention. And exempting adjustments that stem from a court's decision in litigation from the budget neutrality principles that would otherwise apply in rulemaking distorts incentives for litigants in a way that would itself encourage strategic behavior. Allowing litigants to escape otherwise applicable budget neutrality constraints might encourage potential litigants to press aggressive statutory interpretations in court. We believe the best policy is the one that returns all parties as close as we can to the situation they would have been in if the 340B Payment Policy had never been adopted. That policy best ensures that the only money actually spent is money authorized to be spent by the statute, independent of any strategic behavior.

While there is no immediate solvency crisis in the Part B Trust Fund, as its stewards we have an obligation to preserve the Fund for future generations. And while we acknowledge that our budget neutrality will affect hospitals' medium-term revenue, we have moderated that effect by spreading out our recovery of unwarranted payments over a period of many years.

We disagree that any reliance on our previous payment increases was reasonable under the circumstances here or that we are wrong to characterize those payment increases as windfalls, regardless of whether hospitals could decline the payments or not. Finally, we are not wrong to characterize those prior payments as windfalls, regardless of whether hospitals could decline the payments or not. No one suggests we could have increased payments for non-drug items and services if we had not decreased payments for 340B drugs, PHE or not. Now that the legal justification for the payments cuts has fallen short, so has any legal justification for the payment increases. We take full responsibility for the legal error ultimately found by the Supreme Court. But agency error does not expand hospitals' statutory

entitlement to Medicare payments. *Cf. Heckler* v. *Community Health Services,* 467 U.S. 51, 62 (1984) (''There is no doubt that respondent will be adversely affected by the Government's recoupment of the funds that it has already spent . . . [but] respondent [may not] claim any right to expand its services to levels greater than those it would have provided had the error never occurred.'') We repeatedly emphasized to the hospital community that we may need to revisit budget neutrality if the 340B Payment Policy were found to be unlawful; it was clear that the payment increases for non-drug items and services were potentially conditioned on the legality of that policy. To that end, the industry filed multiple briefs disputing our budget neutrality position in court.

Comment: Several commenters stated that CMS's approach to budget neutrality is inconsistent with its past practices. These commenters argue that CMS did not budget neutralize past changes made to budget neutral systems, such as the OPPS clinical diagnostic laboratory services (citing 80 FR 70354),[28] as well as changes to the Inpatient Prospective Payment System wage index (citing § 412.64(e)(1)(ii)) and outlier adjustments (citing 88 FR 27222–23).[29] They contend that CMS has previously applied budget neutrality retroactively only when expressly authorized to do so by Congress.

Response: Commenters' past examples are not analogous to the remedy payment in this rule. Most of these adjustments are examples where CMS's projections of utilization or some other threshold did not meet a projected target. 80 FR 70353 (explaining agency ''overestimated the adjustment necessary to account for the new policy to package laboratory tests''); 88 FR 27223 (noting ''the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2022''). In those cases, CMS declined to make a retroactive budget neutralization adjustment based on updated data. 80 FR 70354 (noting adjustment ''would not recoup 'overpayments' made for'' past years); 88 FR 27223 (''[W]e do not make retroactive adjustments to outlier payments'' to update projections). Commenters correctly point out that CMS also has sometimes corrected past projections when expressly authorized by Congress. (72 FR 47186; 78 FR 50515–16.)

As we previously explained, CMS is not in this rule revising its budget neutrality factor to update its factual assumptions, *i.e.,* the difference between the estimated and actual budget impact of the 340B Payment Policy. Instead, it is unwinding the legal consequences of an unlawful payment policy. Those two changes are different. When we first implemented the 340B Payment Policy, we also underestimated how much hospitals would ultimately dispense those drugs. We thus failed to increase non-drug payments and services by the amount needed fully to offset the payment cuts to 340B-acquired drugs. But under our consistent approach not to update our factual assumptions underlying our projections, we are not updating our estimation in this final rule. Updating that estimation would require *recalculating* the 3.19 percent payment adjustment for non-drug goods and services so that the new rate would reflect the full $10.6 billion that CMS in fact saved under the cuts for 340B-acquired drugs. Instead, CMS is simply *reversing* that 3.19 percent payment increase it implemented beginning in CY 2018 for non-drug goods and services, unwinding its legal error so that parties are as close as possible to the same position as they would have been in had CMS set the legally correct payment rates back in CY 2018. This approach—unwinding an unlawful payment policy while not updating factual projections—is consistent with CMS's general approach to budget neutrality.

Commenters are also wrong that the general IPPS wage index budget neutrality regulation they cite exempts adverse wage index judicial decisions from budget neutrality. Instead, it addresses specific statutory exemptions to the general budget neutrality rule. *See* 86 FR 45176 (discussing § 412.64(h)(4)(vii)) and 75 FR 50160 (discussing § 412.64(e)(4)); *see also* SSA § 1886(d)(3)(E)(i). The regulation addressing adverse wage index judicial decisions is silent on the issue of budget neutrality. *See* 42 CFR 412.64(*l*) (''[I]f a judicial decision reverses a CMS denial of a hospital's wage data revision request, CMS pays the hospital by applying a revised wage index that reflects the revised wage data as if CMS's decision had been favorable rather than unfavorable.''). Commenters point to no wage index decision that is inconsistent with the budget neutrality policy in this rule, even assuming the policy would apply equally to IPPS.

Comment: Several commenters claimed that non-budget neutral remedies are not the result of a *de minimis* exception to a requirement to budget neutralize as claimed by CMS, and that any *de minimis* exception lacks any statutory basis.

Response: We explained in section I.A of this final rule how we have approached budget neutrality when a post-rulemaking payment change would have a *de minimis* impact on estimated OPPS payments, and in section II.B.1 of this final rule why the remedies to which commenters have pointed are consistent with that policy. As an initial matter, we disagree that this interpretation of budget neutrality is not based in the statute. As we explained in the proposed rule, section 1833(t)(9) of the Act (42 U.S.C. 1395*l*(t)(9)) instructs us to budget neutralize OPPS based on the amount of ''estimated expenditures.'' Because there is a certain amount of approximation inherent in the term ''estimate,'' its use authorizes us to round to $0 payment amounts that would have only a *de minimis* impact on estimated expenditures. *See* ''Estimate,'' Merriam-Webster Dictionary (''to judge tentatively or approximately the value, worth, or significance of'').[30] It makes sense that a Congress concerned about cost containment, *see* H.R. Rep. No. 106–436, at 33–34 (1999), would direct the agency to account for significant budgetary impacts, while giving the agency some discretion with how to handle minor payments that would not meaningfully impact the Part B Trust Fund.

Even if commenters were correct, however, that we have not applied our budget neutrality policy precisely as we articulated in the proposed rule and here, we still believe we should adopt this understanding of budget neutrality as the appropriate policy to apply in this case and going forward. It protects the public fisc, the Medicare Trust fund, and beneficiaries against expenditures that prove to not be authorized by law while accounting for the burden and cost to the agency and providers of making after-the-fact changes to a principally prospective payment system.

[28] These commenters also return to the example of *H. Lee Moffitt Center & Research Hospital* v. *Azar,* 324 F. Supp. 3d 1, 15 (D.D.C. 2018), where the court commented that in 2007, HHS retroactively adjusted payment rates to several rural hospitals without offsetting recoupments to achieve budget neutrality We addressed that example above.

[29] One commenter suggested that CMS never updated budget neutrality calculations in the Physician Fee Schedule (PFS) after incorrectly predicting how often certain new PFS codes would be utilized. The commenter failed to cite any source for this comment, but even assuming the commenter is correct that we have mis-projected utilization for certain PFS codes, that is just another example of a factual projection that we routinely do not update, as explained below.

[30] *https://www.merriam-webster.com/dictionary/estimate.*

Comment: Some commenters argued that CMS should not budget neutralize since no court ruling has required budget neutrality and no court has found that hospital payments for non-drug items and services in CYs 2018–2022 were unlawfully paid or received (despite the unlawful reduction in 340B payments resulting in increases to those rates). These commenters point out that the Supreme Court only ruled that the Secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs. The Court explicitly decided not to address arguments regarding budget neutrality. Likewise, the District Court's subsequent order vacating CMS's 340B reimbursement rate for the remainder of 2022 did so without requiring any offset for budget neutrality.

Similarly, one commenter suggested that, as an alternative to offsetting payment, CMS rely on Section 1870 of the Act (42 U.S.C 1395gg) to recover payment. This statute describes when and how CMS may recover incorrect payments it makes on behalf of an individual. The commenter states that, while it does not authorize CMS to offset payments to account for an overpayment, its approach is ''far more rational, and limited, than CMS's overbroad proposal.'' The commenter further encourages CMS to rely on 42 U.S.C 1395gg because, in addition to addressing overpayments on a beneficiary-specific basis, it also permits CMS to forgo recovery where the individual for whom the incorrect payment was made was without fault and making the adjustment would ''defeat the purposes of subchapter II or subchapter XVIII or would be against equity and good conscience.''

Response: When we implemented the payment reduction for 340B-acquired drugs in CY 2018, we also implemented a corresponding increase to the OPPS conversion factor that increased the OPPS payment for non-drug items and services. When the payment reduction for 340B-acquired drugs was eliminated for CY 2023 after the Supreme Court found the policy unlawful, we increased 340B drug payments and correspondingly decreased the OPPS conversion factor. As we have made clear throughout the litigation and in prior rulemaking, the increases in OPPS payments for non-drug items and services were directly and inextricably linked to the decreases in payments for 340B-acquired drugs. But for the reductions in the 340B drug payments, we would never have increased payments for the non-drug items and services; therefore, we believe that if the 340B payments are invalid, then the increased payments for non-drug items and services are invalid, too. While we acknowledge that litigants challenged only the payment increase, when we have made clear that two payment adjustments are so closely linked so that they are really part of the same policy, we believe the policies should rise and fall together regardless of artful pleading strategies. While commenters are correct that the increase to non-drug items and services were authorized under our read of the statute at the time they were promulgated, they omit that this statutory authorization hinged on payment reductions that the Supreme Court held exceeded our statutory authority.

We also do not agree with the commenter's invitation to rely on section 1870 of the Act (42 U.S.C. 1395gg) to forego recovery. Section 1870 speaks to the issue of when providers can shift liability to beneficiaries for overpayments, which can in turn be waived in certain circumstances. *See* section 1870 of the Act. It is silent about the situation here where CMS adjusts future payments through its budget neutrality authority. We believe that given the close connection between the illegal decreased payments for 340B-acquired drugs and the increased payments for non-drug items and services, and the impact of failing to budget neutralize these payments on the public fisc and beneficiaries, section 1833(t) of the Act (42 U.S.C. 1395*l*(t)) applies rather than section 1870 of the Act (42 U.S.C. 1395gg).

Comment: One commenter recommended that CMS work with Congress to forgo an offset.

Response: We appreciate the commenter's recommendation. As noted, legislative changes would require Congressional action.

Comment: One commenter noted that implementing a prospective adjustment poses challenges due to the varying volumes and services that change from year to year at each facility, and that consequently any prospective payment reduction would lead to inaccuracies in the calculation. Due to the inability to properly match prospective adjustments to prior increased payments, this commenter suggests that CMS not finalize any prospective adjustments.

Response: We recognize that there are challenges to implementing our budget neutrality offsets prospectively and that the amount we collect from hospitals imperfectly offsets the amount by which the 340B Payment Policy increased each hospital's payments for non-drug services and items. We disagree, however, that the alternative to a prospective budget neutrality adjustment is no budget neutrality adjustment. Rather, to stay consistent with the statute, the alternative is a one-time debit for the increased payments, as discussed in section II.A. We discussed why we did not select that approach above, and given that decision, our proposed approach properly applies the budget neutrality principle as evenly as possible, even if the calculations may not prove to be to-the-penny exact. *See Shands Jacksonville Med. Ctr.,* 959 F.3d at 1119 (agency may weigh ''the competing values of finality and accuracy'').

Comment: One commenter supported our proposed budget neutrality adjustment and suggested that, if interest cannot be paid on the lump sum payments, CMS withhold the budget neutral payment reductions from 340B providers for the number of years required to equal the value of interest payments.

Response: We appreciate the commenter's suggestion, however, as described earlier in this rule, we lack the authority to pay interest on the lump-sum payments regardless of whatever method or mechanism might facilitate the payment of such interest.

Comment: MedPAC supported our proposed budget neutrality adjustment, arguing that since the reduced 340B payments were implemented in a budget neutral manner in CY 2018, any remedy should likewise be budget neutral. It additionally indicated that, of all of the alternatives CMS considered, CMS selected the best option. However, MedPAC was concerned about the effect of the immediate lump sum payment and 16-year recoupment on the Medicare premium. It requested that the reduction in payment rates be aligned with the remedy payments so that the effects on the Part B premium and Part B finances are mitigated. MedPAC also expressed concern that reducing the payment rates for non-drug items and services could cause inequities because some hospitals will come out net winners or net losers and requested that CMS consider ways to reduce these inequities if they are significant enough. For example, the commenter suggests, CMS could require hospitals to list on their cost reports the revenue gained from 2018 to 2022 and the revenue decrease from the 0.5 percent reduction and then use the cost reports to make reconciliations.

Response: We thank MedPAC for its support for our proposed budget neutrality adjustment. While we appreciate its concern about the remedy's effect on the Medicare Part B

premium, we believe the proposed prospective offset is appropriate in order to minimize the financial burden on hospitals, especially given the difficulties caused by the COVID–19 PHE. On similar issues of concern, such as the prospective offset start date, many commenters argued that hospitals are suffering from financial challenges of unprecedented workforce shortages, inflation, supply chain disruptions, eroding margins, cost increases due to increases in supplies and staffing costs and the lingering effects of the COVID–19 PHE. We believe it is appropriate to take those factors into consideration here as well. And we expect beneficiaries to obtain the benefit of a lower Part B premium in future years as the budget neutrality adjustment is implemented. As acknowledged previously, there is often some inherent imprecision in budget neutrality calculations. However, given these unique circumstances, coupled with the operational challenges posed by the commenter's suggestion, we believe our proposed approach properly applies the budget neutrality principle in a fair, reasonable manner, even if it results in some unavoidable imprecision. *See Shands Jacksonville Md. Ctr.,* 959 F.3d at 1120 (agency need not ''precisely compensate each hospital for payments that were reduced'').

Comment: Another commenter supported our proposed budget neutrality adjustment but requested that recoupment occur over a shorter timeframe than 16 years. The commenter proposed 5 years as a possible timeframe, which, in their view, would be the same amount of time that the conversion factor was ''artificially inflated'' as a result of payment to 340B hospitals at ASP minus 22.5 percent. Alternatively, the commenter suggested offsetting a fixed dollar amount each year over a fixed period of time. For example, dividing 7.8 billion by 5 in order to offset $1.56 billion per year from CY 2024 to CY 2028 by making an adjustment to the conversion factor to reflect an estimated $1.56 billion reduction in non-drug items and services spending for each year.

Response: We appreciate the commenter's suggestion for the offset to be implemented over a shorter timeframe than 16 years; however, we believe that the proposed 0.5 percent annual reduction properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities.

Comment: One commenter recommended that CMS increase the budget neutrality adjustment for OPPS non-drug items and services and apply it over a shorter time frame. This commenter agreed with us that some imprecision in calculating budget neutrality adjustments is unavoidable. However, the commenter contends that CMS unnecessarily exacerbates the imprecision by choosing to recoup budget neutrality payments over a 16-year period rather than a shorter time frame. In the commenter's view, this time frame increases the chance that the relative and absolute amounts of non-drug services furnished by hospitals will deviate from what they were under the original budget neutrality adjustment and that the magnitude of these deviations will increase. The commenter argues that it is appropriate to go with a greater reduction rate because (1) the original budget neutrality adjustment increased payment for OPPS non-drug items and services by 3.19 percent per year, over six times higher than the adjustment proposed by CMS; and (2) Part B reimbursement of hospitals has grown at a rate of 5 percent per year on average between 2017 and 2021 (roughly 4 percent when excluding spending on separately payable drugs under the OPPS). The commenter also argues that CMS should recoup $10.5 billion rather than the proposed $6.2 billion. The commenter proposes three alternative recoupment scenarios with annual budget neutrality adjustments that are greater than the 0.5 percent proposed reduction in OPPS non-drug items and services. Scenario 1 would impose a 1.25 percent annual reduction, which would recover the $7.8 billion within 8 years (or 10 years for the commenter's recommended 10.5 billion). Scenario 2 would impose a 2.25 percent annual reduction, which recover the $7.8 billion within 5 years (or 7 years for the commenter's proposed 10.5 billion). Scenario 3 would impose a 3 percent annual reduction, which would recover the $7.8 billion within 4 years (or 5 years for the commenter's proposed 10.5 billion).

Response: We appreciate the commenter's suggestion to increase the budget neutrality adjustment and apply it over a shorter time frame and the detailed examples of how we might do so. However, as we stated previously, we believe that the proposed 0.5 percent annual reduction (and resulting 16-year implementation timeframe) properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome on impacted entities. Additionally, while we understand the rationale behind prospectively offsetting $10.6 billion, standard remedial principles and basic fairness support situating hospitals as closely as possible to the financial situation they would have been in absent the 340B Payment Policy. That means ensuring hospitals receive $10.6 billion (between the one-time lump sum remedy payment of approximately 9.0 billion and the processing, and reprocessing, of CY 340B 2022 claims of approximately 1.6 billion) for 340B drugs and ensuring a corresponding $7.8 billion is offset in order to maintain budget neutrality.

Comment: One commenter recommended that CMS incorporate recoupment estimates into the calculation of retrospective lump sum payments. Under this suggested arrangement, providers would be paid a ''net'' lump sum payment. The commenter suggested that, if this results in a significant debt for a provider, then CMS should provide an interest-free, flexible, long term repayment plan.

Response: We thank the commenter for this suggestion. This proposed approach is similar to the option discussed previously in section II.A of this final rule.3, titled ''*Aggregate Hospital Payments from CY 2018 Through September 27th of CY 2022*.'' Please see that section for our consideration of this approach.

Comment: One commenter requested clarification regarding the impact of the proposed 16-year OPPS conversion factor reduction on the ASC payment system. The commenter referenced the CY 2023 OPPS final rule in which CMS stated that changes to the OPPS conversion factor do not impact the ASC conversion factor but that there may be an indirect impact on ASC payments for device-intensive procedures. The commenter requests that CMS provide a more detailed assessment of the impact of its proposed 340B remedy on ASC payment rates. Specifically, the commenter requests additional details on the magnitude of the change in payments for device-intensive procedures with and without the OPPS conversion factor reduction. The commenter recognizes CMS's acknowledgement that specific provider types would experience differentiated reimbursement outcomes depending on how much of their payments are based on the OPPS conversion factor, but the commenter believes that CMS should specifically address the impact of its

proposed remedy on the ASC payment system via a regulatory impact analysis.

Response: We thank the commenter for expressing this concern, and we note that all impacts of this prospective offset to the OPPS conversion factor on other payment systems in a particular year will be discussed during that year's applicable rulemaking cycle, including the specific issues that are raised by this commenter.

Comment: Nearly all commenters supported a CY 2026 start date for the initiation of the adjustment to the conversion factor to provide hospitals with additional time to make necessary arrangements. These commenters cited various rationales, including the extraordinary financial challenges caused by unprecedented workforce shortages, inflation, supply chain disruptions, eroding margins, cost increases due to increases in supplies and staffing costs and the lingering effects of the COVID–19 PHE. One commenter supported finalizing the proposed CY 2025 start date, arguing that hospitals do not need additional time to make necessary arrangements since they have known since the date of the Supreme Court decision that they would not be permitted to keep the windfall they received from CY 2018 through CY 2022.

Response: Based on the broad support to start the adjustment to the conversion in CY 2026 among commenters, we believe finalizing a CY 2026 start date for the initiation of the adjustment to the conversion factor is appropriate to provide entities additional time to prepare for the new payment rates. We agree with commenters that an additional year would allow more time for hospitals to recover from the financial challenges described above and to assess and prepare for the new payment rates that will be calculated using a reduced conversion factor. We appreciate the input of the commenter who supported finalizing the start date as proposed. As noted elsewhere in the rule, we agree that hospitals have been on notice about a potential budget neutrality adjustment for quite a while. But hospitals did not know the details of our proposed policy until we issued the proposed rule, and so we believe an additional year to prepare is merited in this unique situation.

Comment: One commenter stated that the proposed rule does not provide sufficient information on the impact of the decreased conversion factor on individual hospitals and requested that CMS provide greater transparency of its calculations by including the budget neutrality calculations related to the recoupment in each future year's OPPS proposed rules.

Response: We appreciate the commenter's suggestion and intend to take it into consideration in future OPPS/ASC rulemaking cycles. We note that the impact of the 0.5 percent reduction to the OPPS conversion factor will be discussed in each year's calendar year OPPS/ASC calendar year rule, including the financial impact on particular groups of hospitals.

Comment: One commenter requested that CMS provide greater clarity on each individual hospital's repayment obligations during the recoupment period. The commenter observed that changes in utilization could make the estimated recoupment period longer or shorter than CMS estimates and expressed concern that this could result in hospitals refunding more in additional payments than they ever received during the CY 2018 through CY 2022 period. The commenter requested that CMS ensure that hospitals not be required to pay more in the recoupment than what they were initially paid in increased non-drug payments during the CY 2018 through CY 2022 time frame.

Response: We acknowledge that it is possible that some individual hospitals refund more in additional payments than they received in non-drug payments. But that is the consequence of structuring payments through a future payment cut rather than, for example, clawing back or recouping increased payment amounts between 2018 through 2022. Our methodology properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome on impacted entities. In the aggregate, we expect hospitals will be prospectively offset approximately the same amount that they received in increased non-drug item and service spending from CY 2018 through CY 2022 as a result of the 340B Payment Policy. And while changes to utilization and other behaviors will leave ''some hospitals slightly better off and others slightly worse off than they would have been had the rate reduction never taken effect,'' such differences are permissible variations inherent in a prospective remedy. *Shands Jacksonville Med. Ctr., Inc.* v. *Azar,* 959 F.3d 1113, 1120 (D.C. Cir. 2020). We have tried to mitigate that effect by limiting the future recoupment to providers that did in fact benefit from the increased payments in the past.

Comment: One commenter expressed concern about the application of the 0.5 percent reduction to new non-drug items and services that were not available from January 1, 2018, through September 27, 2022, and which, therefore, were not reimbursed at the higher rate. This commenter requested that CMS create a system that excepts items and services that are new since October 1, 2022, from the 0.5 percent reduction. The commenter suggested that this could be accomplished with the creation of a new status indicator that would alert MACs to the service being new post-October, which could then be adjudicated at the MAC level using the same methods applied to take the adjustment for sequestration. Similarly, one commenter urged CMS to consider other factors that could impact the recoupment and address them in the final rule. The commenter specifically asked for clarification as to how hospital closures during the recoupment period would impact other hospitals' repayment obligations during the recoupment period and if hospitals that remain open would be required to shoulder the debt associated with the closed hospitals.

Response: To begin, if for any reasons the number of hospitals paid under the OPPS that are subject to the prospective offset decrease, that will not impact the total amount of the offset. Otherwise, changes in what items and services providers bill to Medicare is one example of the changes to utilization and other behaviors discussed above in the preceding comment. As we acknowledge here, those changes will inevitably lead to some distributive effects, but we have done what we can to mitigate that effect by limiting the future recoupment to providers that did in fact benefit from the increased payments in the past. Specifically, exempting new items and services from this payment adjustment may distort providers' incentives to prescribe items and services based on whether they existed between CY 2018 and 2022 rather than whether they are medically appropriate, potentially impacting the care providers give to beneficiaries. And the more exceptions we create, the more complicated we make the payment reduction. Complications increase the risk of delays or errors in implementing this final rule.

Comment: Many commenters argued that budget neutrality adjustments will have severe negative impacts on hospitals and might impair hospitals' ability to continue providing services to vulnerable patients/communities. Various commenters requested that rural hospitals, free-standing children's hospitals, free-standing cancer hospitals

and safety-net hospitals be excluded from the prospective offset.

Response: We acknowledge that our proposal to decrease future payments will have a financial impact across all hospitals paid under the OPPS, except for new providers as described below, and we are particularly mindful of the impact on vulnerable patients and communities. But future decreases are, on aggregate, the mirror image of prior payment increases that, as we have repeatedly stated, would otherwise be a windfall to providers. And such windfalls are not cost-free; as we noted previously, the costs are ultimately borne by beneficiaries and taxpayers—including the vulnerable patients and communities to which commenters themselves refer. Additionally, we note that under section 1833(t)(7)(D)(ii) of the Act (42 U.S.C. 1395*l*(t)(7)(D)(ii)), cancer and children's hospitals receive transitional outpatient payments (TOPs) which permanently hold them harmless to their ''pre-Balanced Budget Act of 1997 (BBA) amount'' as specified under the terms of the statute. These hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS.

After consideration of the comments received, and for the reasons stated in the proposed and in this final rule, we are finalizing our policy largely as proposed. We believe that sections 1833(t)(2)(E) and (t)(14) of the Act (42 U.S.C. 1395*l*(t)(2)(E) and (t)(14)), under which we proposed to make this proposed remedy payment, are properly read to require budget neutrality. We are finalizing that budget neutrality will be maintained through a 0.5 percent reduction to the OPPS conversion factor over an estimated 16-year time period until a total of $7.8 billion is offset. As previously mentioned, we were convinced by commenters that we should start the prospective offset in CY 2026. As such, we are codifying the 0.5 percent reduction in the OPPS conversion factor effective for CY 2026 in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32. The exact impact on OPPS payment rates as a result of this reduction will be reflected in the annual OPPS/ASC proposed and final rules. *See* Table 2 for an illustration of this finalized payment mechanism.

BILLING CODE 4120–01–P

TABLE 2: ILLUSTRATION OF THE FINALIZED 0.5 PERCENT CONVERSION FACTOR ADJUSTMENT TO THE OPPS NON-DRUG ITEMS AND SERVICES BEGINNING CY 2026 TO MAINTAIN BUDGET NEUTRALITY

	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	$66,910	$70,256	$73,769	$77,457	$81,330	$85,369
0.5-Percent Payment Reduction Amount (millions)	$0	$351	$369	$387	$407	$427
Estimated Total Cumulative Offset (millions)	$0	$351	$720	$1,107	$1,514	$1,941

	CY 2031	CY 2032	CY 2033	CY 2034	CY 2035	CY 2036
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	$89,667	$94,150	$98,858	$103,801	$108,991	$114,440
0.5-Percent Payment Reduction Amount (millions)	$448	$471	$494	$519	$545	$572
Estimated Total Cumulative Offset (millions)	$2,389	$2,860	$3,354	$3,873	$4,418	$4,991

	CY 2037	CY 2038	CY 2039	CY 2040	CY 2041
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	$120,162	$126,170	$132,479	$139,102	$114,440
0.5-Percent Payment Reduction Amount (millions)	$601	$631	$662	$695	$188*
Estimated Total Cumulative Offset (millions)	$5,591	$6,222	$6,885	$7,580	$7,769

**Note, the final year's offset is estimated to be less than 0.5 percent in order to meet the total estimated offset of $7.8 billion (rounded).*

We also note the Total Applicable OPPS Non-Drug Item and Service Spending are estimates based on an assumption of 5 percent annual growth. The 5 percent annual growth is determined from a 10-year baseline percentage increase.

BILLING CODE 4120–01–C

c. Exclusion of New Providers

In the proposed rule (88 FR 44080), CMS recognized that any hospital that enrolled in Medicare after January 1, 2018, received less than the full amount of the increased non-drug item and service payments made during that time than they otherwise would have received if enrolled prior to that date. As we explained in that rule, this was because the increased non-drug item and service payments were being paid during all of CY 2018 through CY 2022, so any hospital that was not enrolled in Medicare for the full duration of that time period did not receive the full amount of increased non-drug items and service payments. We noted that, while the 340B drug payments increased to the default rate effective September 28,

2022, following the Supreme Court's decision, the increased conversion factor and associated increased non-drug item and service payments were in effect until December 31, 2022. We therefore proposed that these providers would not be subject to the prospective rate reduction, which was predominantly designed to offset those non-drug item and service payments made during CY 2018 through CY 2022.

Consequently, in the proposed rule, we proposed to designate any hospital that enrolled in Medicare after January 1, 2018, as a ''new provider'' for purposes of the conversion factor adjustment to offset those additional expenditures by Medicare to remedy the 340B Payment Policy and to pay these hospitals the rate for non-drug items and services that would apply in the absence of the conversion factor adjustment implemented due to the 340B Payment Policy remedy. As we explained, that meant that we would calculate payment rates for new providers using the conversion factor before applying the proposed 0.5 percent annual adjustment that would apply for hospitals that are not ''new providers'' for purposes of this policy. For the purpose of designating a new provider, we proposed the date of enrollment in Medicare as the provider's CMS certification number (CCN) effective date. Providers that met this definition, and that we proposed would be excluded from the prospective payment adjustment, were listed in Addendum BBB to the proposed rule. This addendum can be found online through the CMS OPPS website.[31] As reflected in this file, we determined that approximately 300 providers out of the approximately 3,900 OPPS providers met this definition. We proposed to codify the exclusion of new providers from the prospective payment adjustment to the conversion factor for the duration of its application in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32.

We also clarified in the proposed rule that the proposed ''new provider'' designation was intended to apply only to truly new providers, meaning those that were not enrolled in Medicare as of January 1, 2018. Our proposal to exclude ''new providers'' from the prospective rate reduction would not apply to providers that were enrolled in Medicare before January 1, 2018, and subsequently had a change in ownership that resulted in a new CCN, in part due to the fact that these providers would have received increased non-drug item and service payments for the duration of the 340B Payment Policy from CY 2018 through CY 2022. We recognized in the proposed rule that this approach would exempt some hospitals receiving the 340B lump sum payment from the prospective offset and explained that we considered creating various levels of exclusion from the prospective offset depending on how long the specific hospital received increased non-drug item and service payments as a result of the 340B Payment Policy. However, we concluded that it was not administratively feasible for CMS, or likely desired by providers, to create many different sets of payment rates for different groups of hospitals for the duration of the proposed 16-year offset period depending on how much of the period of CY 2018 through CY 2022 the provider was enrolled in Medicare. Consequently, we proposed that any hospital that enrolled in Medicare after January 1, 2018, would be exempt from the annual adjustment to the conversion factor to offset lump sum payments to affected 340B covered entity hospitals. We explained that we were proposing to exempt those hospitals because they received less than the full amount of the increased non-drug item and service payments made during CY 2018 through CY 2022 due to the 340B Payment Policy than they otherwise would have received if enrolled prior to that date.

We solicited comments on our proposed definition of a ''new provider'' and our proposal to exempt new providers from the annual adjustment to the conversion factor to offset lump sum payments to affected 340B covered entity hospitals. We also solicited comments on whether there were any other easily identifiable categories of providers who should be similarly exempted from the annual adjustment to the conversion factor.

We received the following comments on our proposals.

Comment: One commenter expressed concern with the breadth of the new provider exemption. This commenter suggested that hospitals should be subject to reduced payment rates for a period of time commensurate with the period of time they benefited from the increased payment rates. For example, the commenter argued, that if a hospital began its Medicare participation on January 1, 2020, the hospital would have benefited from the increased payment rates for 3 years (2020–2022) which is 60 percent of the time that the increased payments were in place. For this hospital, the commenter argued, CMS would require that the reduced payment rates would apply for 60 percent of the time CMS expects the reduced payments to be in place (9.6 years for 16-year timeframe).

Response: We acknowledge that a more individualized application of the exception would lead to more precise adjustments and potentially decrease the distributive effects discussed above. However, consistent with our general approach in this rule of complying with the budget neutrality requirement while avoiding undue administrative burdens, we believe that such an approach is not feasible because it would result in many different lengths of payment or OPPS conversion factor adjustments. The more complicated we make the payment reduction, the closer it approaches re-processing all payments—an approach we rejected previously in section II.A of this final rule. And as noted above, complications increase the risk we will face delays or errors in implementing this final rule.

Comment: Another commenter appreciated the exclusion of new providers but expressed concern that over the long term the exclusion could either be overlooked or reversed due to future rulemaking and reimbursement adjustments.

Response: While there is always the risk of inadvertent error, we believe we have clearly defined the universe of qualifying providers, and so we believe the risk of overlooking them is relatively low. Should we choose to change our policy in the future, we would do so through notice and comment rulemaking, and interested parties would have the opportunity to express their concerns. Hospitals that will be excluded under the prospective payment adjustment are listed in Addendum BBB to this final rule. This addendum can be found online through the CMS OPPS website.[32] During subsequent annual rulemaking, an updated addendum of hospitals will be included in that year's calendar year OPPS/ASC rule. Any errors or omissions in the addenda should be addressed through the public notice and comment period for that year's rule.

After considering the comments received, we are finalizing our policy as proposed, and will designate any hospital that enrolled in Medicare on or after January 2, 2018, as a ''new provider'' and will pay these hospitals the rate for non-drug items and services that would apply in the absence of the conversion factor adjustment implemented due to the 340B Payment Policy remedy. This means that we will calculate payment rates for new

[31] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

[32] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

providers using the conversion factor before applying the 0.5 percent annual adjustment that would apply for hospitals that are not ''new providers'' for purposes of this policy.

We are codifying the exclusion of new providers from the prospective payment adjustment to the conversion factor for the duration of its application in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32 as proposed, except we are adding ''biologicals'' to the reference to separately payable drugs. We are adding ''biologicals'' to the regulation text at 419.32 in order to ensure that the regulation text matches our finalized policy regarding the calculation of prospective payment rates for hospital services and the exclusion of separately payable drugs and biologicals from that prospective payment rate.

d. Additional Comments Received

Comment: We received a couple of comments asking for CMS to use its current drug acquisition survey to inform OPPS 340B payment rates. Similarly, we heard from commenters that we should conduct another survey. Further, commenters requested we make changes to how Medicare pays for 340B-acquired drugs. Similarly, commenters asked for reform to the 340B Program as a whole.

Response: We appreciate these comments but many of them are out of the scope of this rule. HRSA manages the 340B Program more generally, and more broad comments with respect to that program are not the subject of this rulemaking. OPPS payment policy will be included in the appropriate year's annual rule. As noted above, we previously suggested that we might use our survey of CY 2018 and 2019 cost data to inform the remedy. (84 FR 61322.) But as we subsequently noted, we received many comments on the survey data, and using that data, which surveyed only 340B hospitals, might not comport with the Supreme Court's decision. Using it would introduce new complexities into the rate calculation, for instance, by requiring consideration of adjustments to the data and other factors (85 FR 86052). We do not believe it is worth delaying the remedy payments to allow for such considerations or for us to conduct a new survey many years after the fact.

Comment: Many commenters expressed concern about Medicare Advantage Organizations (hereinafter referred to as ''MAOs'') realizing a ''windfall'' as a result of reducing outpatient payments without making corresponding repayments to hospitals. Specifically, these commenters argued that MAOs will see the benefit of reducing outpatient payments to all hospitals for non-drug items and services by 0.5 percent starting in CY 2026 but will not be required to repay affected 340B covered entity hospitals the amounts that were withheld for 340B drugs from 2018 through 2022. These commenters requested that CMS consider several courses of action to ensure MAOs fully comply with the remedy.

Response: We appreciate commenters' concerns; however, these comments are out of the scope of this final rule. We refer commenters to the Hospital Outpatient Prospective Payment System Update on Payment Rates for Drugs Acquired through the 340B Program—Informational for MAOs memorandum that was issued by CMS on December 20, 2022.[33] In that memorandum, we summarized the issue with the Outpatient Prospective Payment system rule related to payments for 340B acquired drugs and provided references to the relevant CMS-issued materials that were issued after the Supreme Court decision that vacated the differential payment rates. We clarified that for Medicare Advantage, MAOs must pay non-contract providers or facilities for services and items at least the amount they would have received under Original Medicare payment rules, in accordance with section 1852(a)(2) of the Act (42 U.S.C. 1395w–22). In accordance with section 1854(a)(6)(B)(iii) of the Act (42 U.S.C. 1395w–22(a)(6)(B)(iii)), CMS may not require MAOs to contract with a particular healthcare provider or use particular pricing structures with their contracted providers. Therefore, MAOs that contract with a provider or facility eligible for 340B drugs can negotiate the terms and conditions of payment directly with the provider or facility and CMS cannot interfere in the payment rates that MAOs set in contracts with providers and facilities.

Comment: A few commenters alleged Accountable Care Organizations will continue to be unfairly impacted by CMS not addressing the disparity between paying for 340B drugs at the lower price of ASP minus 22.5 percent in ACO benchmarks (that is, between 2018–2022) and the higher price of ASP plus 6 percent in performance years. The commenters urge CMS to correct this disparity by adjusting its calculation of ACOs' performance year expenditures to correct for this difference without ACOs having to early renew. The commenters argued an adjustment would help ACOs that include ACO providers/suppliers that are 340B providers, who help under-served patients and address the health disparities CMS wants to eliminate through policymaking.

Response: The Shared Savings Program includes Parts A and B fee-for-service claims and individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program in benchmark and performance year expenditure calculations. Historical benchmark year expenditures are risk-adjusted, and a blend of national and regional growth rates are used to trend forward expenditures for each benchmark year (benchmark year 1 and 2) to benchmark year 3. Benchmark expenditures are further updated by trending forward to the performance year during financial reconciliation. Risk adjustment is applied to account for changes in severity and case mix of the ACO's assigned beneficiaries between the benchmark period and the performance year, and the use of a blended national and regional trend adjusts an ACO's historical benchmark expenditures to remain comparable to changes in performance year expenditures including changes in Medicare payment policy and other factors affecting expenditures. The payment rate for 340B-acquired drugs included in Shared Savings Program PY 2023 financial calculations will be ASP plus 6 percent. For ACOs participating in PY 2023 that have historical benchmark years for which payments for 340B-acquired drugs were based on the ASP minus 22.5 percent rate (2018–2022), the differences between the 340B-acquired drug payments included in historical benchmark year and performance year expenditure calculations have the potential to be mitigated when CMS updates the benchmark using a blend of national and regional growth rates. Additionally, for ACOs with agreement periods starting January 1, 2024, we finalized policies through rulemaking that may also support ACOs impacted by the changes in 340B-acquired drug payment rates, such as policies to reduce the impact of the negative regional adjustment, incorporate a prior savings adjustment in historical benchmarks for renewing and re-entering ACOs, and modifying the methodology for updating the historical benchmark to incorporate a prospective, external factor. These policies are expected to encourage new and continued participation from ACOs serving medically complex and high cost of care populations.

[33] Available at *https://www.cms.gov/files/document/cmsopps340bupdate508g.pdf.*

Any adjustments to 340B-acquired drug claims with CY 2022 dates of service that were processed on or before March 31, 2023, are reflected in Medicare Shared Savings Program (Shared Savings Program) expenditure calculations used in Performance Year (PY) 2022 financial reconciliation and will be used to calculate historical benchmarks for ACOs for which CY 2022 is a benchmark year. Any adjustment to claims with CY 2022 dates of service that were processed after March 31, 2023, or that have not yet been submitted or processed are not reflected in PY 2022 Shared Savings Program expenditure calculations and would not be used to calculate historical benchmarks for ACOs for which CY 2022 is a benchmark year.

Additionally, CMS will provide lump-sum payments to providers that received reduced reimbursement for 340B-aquired drugs from CY 2018 through September 27th of CY 2022, such lump sum payments will be adjusted to ensure that CMS does not make duplicate payments for claims that had already been reprocessed at the higher payment rate. These lump sum payments will not be included in Shared Savings Program calculations, as these payments would not be individually beneficiary identifiable.

Comment: One commenter urged CMS to consider recommendations outlined in the ASCO 340B drug pricing reform statement in any future approach to reforming the 340B Program. The commenter requested that when proposing further policy changes and updates, CMS analyze the impact of the policies, including whether the proposals satisfy the original intent of the legislation, the presence or absence of appropriate safeguards for compliance and oversight, and the unique considerations related to cancer patients and other vulnerable patients.

Response: We appreciate the commenter's concerns; however, this comment is out of the scope of this final rule.

Summary of Finalized Policy

As discussed in the preceding sections, after consideration of the public comments we received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing the proposed remedy for the 340B Payment Policy for CYs 2018–2022, with the one exception that we are changing the implementation date of the 0.5 percent adjustment from CY 2025 to CY 2026. Using our authority under sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395*l*(t)(14) and (t)(2)(E)) and, to the extent necessary, section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)), we will make a one-time lump sum payment to each affected 340B covered entity hospital calculated as the difference between what the affected 340B covered entity hospital received for 340B-acquired drugs during the time period at issue and approximately what they would have received for 340B-acquired drugs if the 340B adjustment had not been in place, which includes what the affected 340B covered entity hospital would otherwise have been paid by the beneficiary. The amount of the lump sum payment that has been calculated for each affected 340B covered entity hospital is listed in Addendum AAA. Following the deadline to submit a request for technical correction to the amount listed in Addendum AAA, we will issue instructions to the Medicare Administrative Contractor (MAC) for each affected 340B covered entity hospital that has not submitted a request for technical correction by the deadline discussed in this rule. We will instruct the MAC to issue a one-time lump sum payment to those hospitals in the amount listed in Addendum AAA within 60 calendar days of the MAC's receipt of the instruction. We will instruct MACs to pay hospitals that submit a request for technical correction through a similar process after the technical correction process is completed, and the payment amount for those providers will be based on the result of the technical correction process. The lump sum payments do not include interest. In aggregate, the lump sum payments we calculate here will total $9.0 billion and will include a portion equivalent to the amount that beneficiaries, through cost-sharing, would have paid hospitals.

To comply with the budget neutrality requirements of the authorities we are relying on to make the one-time lump sum remedy payments, and alternatively relying on our equitable adjustment or common-law and inherent recoupment authorities, beginning in CY 2026, we will reduce all payments for non-drug items and services to all OPPS providers, except new providers (hospitals with a CMS CCN effective date of January 2, 2018, or later), by 0.5 percent each year until the total estimated offset of $7.8 billion is reached. We currently estimate that the payment decrease will be completed after approximately 16 years. To implement this reduction and exception for new providers, we are finalizing the proposed regulation text changes at § 419.32(b)(1)(iv)(B) as proposed, except for changing the implementation date of the 0.5 percent reduction from CY 2025 to CY 2026.

III. Collection of Information Requirements

This document does not impose information collection requirements; that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Regulatory Impact Analysis

Comment: One commenter alleged that there is a significant discrepancy in CMS's total OPPS payments data, which could impact how long it would take for CMS to effectuate any recoupment. Specifically, the commenter argued that there is a $23 billion dollar discrepancy between the amount of total OPPS payments stated in the proposed 2024 OPPS rule ($88.6 billion) and the amount of OPPS payments for all providers stated in the OPPS impact file for the proposed 2024 OPPS rule ($65.65 billion). The commenter expressed concern about this discrepancy and its effect on individual hospitals and the 16-year recoupment period.

Response: We agree that there are differences between the spending numbers in the OPPS impact files versus overall OPPS spending estimates. The OPPS impact file associated with each proposed and final rule primarily displays the effects of current and prospective policies based on historical claims. It also excludes lines from estimated payment that are removed from the ratesetting process for OPPS purposes. In contrast, the overall OPPS spending estimate is based on projections of future spending and include estimated changes in enrollment, utilization, and case mix. We also agree that things may change over the course of the 16-year recoupment period, and we will monitor the impact of these prospective reductions as well as recoupment amounts over the course of that time period.

A. Statement of Need

From CY 2018 through September 27th of CY 2022, CMS paid a lower rate (generally ASP minus 22.5 percent) to certain hospitals for drugs acquired through the 340B discount program. The purpose of this policy was to pay these hospitals for 340B drugs at a rate that more accurately reflected the actual costs they incurred to acquire them. This 340B policy was the subject of

several years of litigation, which culminated in a decision of the Supreme Court of the United States in *American Hospital Association* v. *Becerra,* 142 S. Ct. 1896 (2022), which held that if CMS has not conducted a survey of hospitals' acquisition costs, it may not vary the payment rates for outpatient prescription drugs by hospital group. The Supreme Court subsequently remanded the case, and the District Court ultimately remanded the case to CMS to implement a remedy to address the reduced payment amounts to the plaintiff hospitals from CY 2018 through September 27th of CY 2022.

This final rule describes the remedy CMS is finalizing to comply with the District Court's remand. It remedies the reduced payment amounts to the affected 340B covered entity hospitals by (1) calculating the amount each hospital would have received for 340B drugs from CY 2018 through September 27th of 2022 had the 340B policy not been in place; (2) subtracting from that total the amount each hospital received for 340B drugs from CY 2018 through September 27th of CY 2022; and (3) paying each affected 340B covered entity hospital the difference between these amounts by issuing instructions to the relevant MAC instructing it to issue a one-time lump sum payment to the hospital. The amount of the lump sum payment includes the portion of the payment amount that would have been paid from the Part B Trust Fund and the portion of the payment amount that would have been paid in the form of beneficiary coinsurance if not for the 340B Payment Policy.

To comply with statutory budget neutrality requirements, we proposed and are finalizing to annually reduce OPPS payments for non-drug items and services beginning in CY 2026 by decreasing the OPPS conversion factor by 0.5 percent each year until a total offset of an estimated $7.8 billion is reached.

B. Overall Impact

We have examined the impacts 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. 96354) (5 U.S.C. 601–612), section 1102(b) of the Act (42 U.S.C. 1302(b), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4) (2 U.S.C. 602), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter referred to as the ''Modernizing E.O.'') amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 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 affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, 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 this Executive order.

A regulatory impact analysis (RIA) must be prepared for rules with significant regulatory action(s) and/or with significant effects as per section 3(f)(1) of Executive Order 12866 ($200 million or more in any 1 year). Based on our estimates, the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) economic effect. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Department has provided the following assessment of their impact.

As required by statute, we are implementing this court-ordered remedy in a budget neutral manner, and we estimate that the total increase in Federal Government expenditures, due only to the changes in this final rule, will be $2.8 billion. We took into consideration the additional Medicare drug payments of $9.0 billion to the estimated 1,700 340B covered entity hospitals to which the drug payment remedy will apply, and the $6.2 billion in reduced Medicare prospective payments for non-drug items and services beginning in CY 2026 to offset the additional payments that were made for non-drug items and services from CY 2018 through CY 2022 as part of the 340B Payment Policy and the amount of the 340B drug remedy payments that would otherwise have been paid by the beneficiary. We note that this $6.2 billion figure is the portion of reduced Medicare prospective payments specifically, and this represents approximately 80 percent of the total $7.8 billion offset that we proposed. Beneficiaries will experience reduced prospective co-insurance payments representing approximately the remaining 20 percent of the total $7.8 billion offset. The $9.0 billion amount is an estimate of the total aggregate additional payments that still need to be made to 340B hospitals for drugs that were paid less due to the 340B policy from CY 2018 through September 27, 2022.

While we consider the amount of additional payment made to affected 340B covered entity hospitals for 340B-acquired drug claims with dates of service from January 1, 2022, through September 27, 2022, that were reprocessed at the default drug payment rate after the 340B Payment Policy was vacated, estimated at $1.6 billion, for purposes of the total aggregate remedy payment to affected 340B covered entity hospitals, we are not including that $1.6 billion in our calculation here, which estimates the total increase in Federal Government expenditures due only to the proposed changes in this final rule. This $1.6 billion in remedy payments has already been made after the District Court's order.

The two amounts described above, $9.0 billion and $6.2 billion, are not equal because the separate amounts associated with restoring 340B-acquired drug payments to ASP plus 6 percent and unwinding the associated 3.19 percent rate increase for non-drug items and services are not equal to each other. This is due to many factors. Some factors that decreased the gap include the facts that Medicare's payment policy adjustment for 340B acquired drugs ended on September 27, 2022, while the original conversion factor adjustment of minus 3.19 percent remained in effect until December 31, 2022, and most of the 340B drug claims with dates of service between January 1, 2022, and September 27, 2022, have already been reprocessed at the higher default drug payment rate, while none of the increased non-drug item and service

payment during this time period have been remedied. By contrast, some factors that increased the gap include the facts that this remedy rule pays 340B providers an amount equivalent to the lost beneficiary cost-sharing 340B providers would have received for 340B-acquired drugs if the 340B Payment Policy had not been in effect as part of the lump sum payments to providers, and the original budget neutrality adjustment to increase the conversion factor in CY 2018 did not keep pace with the reduction in 340B drug payments for the remainder of the years for which the 340B Payment Policy previously applied. In aggregate, the total additional payment that providers will receive as a result of this remedy, $10.6 billion, will be larger than the amount of payment that will be prospectively offset, $7.8 billion.

To explain the last factor in more detail, from CY 2018 through CY 2022, the actual spending associated with 340B-acquired drugs changed from what we projected in the CY 2018 OPPS/ASC final rule with comment period. As we noted above in section II.B.2 of this final rule, the actual total reduction in 340B-acquired drug payments during this time period outpaced the corresponding increase in non-drug item and service payments. This final rule maintains budget neutrality by undoing the original 340B Payment Policy. This approach is consistent with how we unwound the 340B Payment Policy prospectively, as described in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71975). There, we maintained budget neutrality by removing the effect of the 340B policy as originally implemented in CY 2018 from the CY 2023 conversion factor, and ensured it was equivalent to the conversion factor that would be in place if the 340B Payment Policy had never existed. We did not increase the rate we paid for 340B-acquired drugs without making a corresponding change to the conversion factor. Nor did we adjust the conversion factor to account for the actual increase in the utilization for 340B drugs. In Table 3 of this final rule, we display the impact of these proposed policy changes on drug payments, including aggregate payment by hospital type. Specific 340B-acquired drug lump sum payment amounts, by individual hospital, can be found in Addendum AAA. The impact for specific hospital types of the reduced prospective payment for non-drug items and services beginning in CY 2026 would be included in each proposed and final rule for calendar years in which the prospective reduction would apply, beginning in CY 2026.

C. Detailed Economic Analysis

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 3 shows the total number of facilities (1,686), including designated cancer and children's hospitals and Community Mental Health Centers (CMHCs), that will receive remedy payments under this final rule. We excluded all hospitals and CMHCs that we do not expect will experience any direct effect from the remedy payments in this final rule. We show the total number of OPPS hospitals (1,686) that will receive remedy payments, excluding the PPS-exempt cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D)(ii) of the Act (42 U.S.C. 1395*l*(t)(7)(D)(ii)) provides transitional outpatient payments (TOPs), which permanently hold harmless cancer hospitals and children's hospitals to their ''pre-Balanced Budget Act of 1997 (BBA) amount'' as specified under the terms of the statute.

Column 2: Remedy for the 340B Payment Policy (in Millions)

Column 2 shows the estimated remedy payments that will be made under this final rule to various categories of affected providers. We note that certain categories of providers may experience limited effects due to either having no providers in the category, or limited billing associated with 340B-acquired drugs. We also note that a provider's placement within the categories may vary due to their characteristic information potentially changing across the years in question (CY 2018 through CY 2022).

Column 3: CY 2022 Reprocessed Payment Differential (in Millions)

Column 3 displays the estimated payment impact of any CY 2022 claims that have been reprocessed by the MACs. We note that these claims, which include dates of service for services furnished prior to September 28, 2022, were not reprocessed their payments otherwise would have been included as remedy payments in Column 2.

Column 4: Total 340B Drug Remedy Payments

Column 4 includes the total remedy payments, which is the sum of column 2 and column 3.

BILLING CODE 4120–01–P

TABLE 3: ESTIMATED FINANCIAL IMPACT OF THE LUMP-SUM REMEDY PAYMENTS ON OPPS PROVIDERS

Row		(1) Number of Hospitals	(2) Remedy Payment (in millions)	(3) CY 2022 Reprocessed Payment Differential (in millions)	(4) Total 340B Drug Remedy Payments (Sum of Columns 2 and 3)
1	**ALL PROVIDERS** *	1,686	9,003.8	1,615.6	10,619.4
2	**ALL HOSPITALS** (excludes hospitals held harmless and CMHCs)	1,655	9,003.5	1,615.5	10,619.0
3	**URBAN HOSPITALS**	1,324	8,543.8	1,562.8	10,106.6
4	LARGE URBAN (GT 1 MILL.)	625	4,322.7	843.8	5,166.5
5	OTHER URBAN (LE 1 MILL.)	699	4,221.1	719.0	4,940.1
6	**RURAL HOSPITALS**	331	453.4	51.3	504.7
7	SOLE COMMUNITY	152	94.2	6.1	100.3
8	OTHER RURAL	179	359.2	45.1	404.3
	BEDS (URBAN)				
9	0 - 99 BEDS	224	259.0	46.6	305.6
10	100-199 BEDS	382	823.9	131.3	955.2
11	200-299 BEDS	253	1,197.3	211.5	1,408.8
12	300-499 BEDS	272	1,980.1	355.2	2,335.3
13	500 + BEDS	193	4,283.4	818.3	5,101.7
	BEDS (RURAL)				
14	0 - 49 BEDS	128	80.3	8.3	88.6
15	50- 100 BEDS	117	101.2	15.8	117.0
16	101- 149 BEDS	41	88.8	9.4	98.2
17	150- 199 BEDS	22	89.9	8.3	98.2
18	200 + BEDS	23	93.2	9.5	102.7
	REGION (URBAN)				
19	NEW ENGLAND	73	609.9	123.7	733.6
20	MIDDLE ATLANTIC	165	1,177.2	244.6	1,421.8
21	SOUTH ATLANTIC	225	1,590.3	289.6	1,879.9
22	EAST NORTH CENT.	236	1,315.4	247.8	1,563.2
23	EAST SOUTH CENT.	75	668.0	113.4	781.4
24	WEST NORTH CENT.	80	749.7	135.3	885.0
25	WEST SOUTH CENT.	149	608.8	104.0	712.8
26	MOUNTAIN	90	564.0	96.1	660.1
27	PACIFIC	228	1,260.5	208.2	1,468.7
28	PUERTO RICO	3	0.0	0.0	0.0

	REGION (RURAL)				
29	NEW ENGLAND	11	25.1	1.4	26.5
30	MIDDLE ATLANTIC	23	32.2	3.6	35.8
31	SOUTH ATLANTIC	54	94.7	8.0	102.7
32	EAST NORTH CENT.	48	67.1	8.1	75.2
33	EAST SOUTH CENT.	77	145.2	20.0	165.2
34	WEST NORTH CENT.	30	6.8	0.7	7.5
35	WEST SOUTH CENT.	54	19.5	1.4	20.9
36	MOUNTAIN	20	28.1	2.9	31.0
37	PACIFIC	14	34.7	5.3	40.0
	TEACHING STATUS				
38	NON-TEACHING	818	1,673.3	291.6	1,964.9
39	MINOR	522	2,780.8	464.0	3,244.8
40	MAJOR	315	4,543.1	858.5	5,401.6
	DSH PATIENT PERCENT				
41	0	0	0.0	0.0	0.0
42	GT 0 - 0.10	31	16.5	0.4	16.9
43	0.10 - 0.16	65	6.9	0.1	7.0
44	0.16 - 0.23	178	54.4	15.7	70.1
45	0.23 - 0.35	728	3,832.4	711.4	4,543.8
46	GE 0.35	642	5,086.9	886.4	5,973.3
47	DSH NOT AVAILABLE **	11	0.1	0.0	0.1
	URBAN TEACHING/DSH				
48	TEACHING & DSH	775	7,168.4	1,308.8	8,477.2
49	NO TEACHING/DSH	539	1,375.3	254.0	1,629.3
50	NO TEACHING/NO DSH	0	0.0	0.0	0.0
51	DSH NOT AVAILABLE2	10	0.1	0.0	0.1
	TYPE OF OWNERSHIP				
52	VOLUNTARY	1,241	7,208.2	1,308.9	8,517.1
53	PROPRIETARY	152	32.1	7.1	39.2
54	GOVERNMENT	262	1,757.0	298.1	2,055.1

Column (1) shows total hospitals that are expected to receive payments related to the 340B policy under this final rule.

Column (2) includes the estimated drug remedy payment made to account for the policies described in this final rule during the time period of CY 2018 through CY 2022.
Column (3) displays the estimated payment impact of any CY 2022 claims that have been reprocessed by the MACs. We note that if these claims, which include dates of service for services furnished prior to September 28, 2022, were not reprocessed their payments would otherwise have been included as remedy payments in Column 2.

Column (4) includes the total remedy payments, which is the sum of column 2 and column 3
* These 1,686 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs. We note that this also includes 22 providers who are not expected to receive 340b remedy payments but who had reprocessed CY 2022 claims.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

BILLING CODE 4120–01–C

We estimate that the total monetary transfer will be approximately $9.0 billion. The $9.0 billion includes the proposed additional lump sum drug

payments to the 1,686 affected 340B covered entity hospitals. The $9.0 billion amount is an estimate of the total aggregate additional payments that will need to be made to the affected 340B covered entity hospitals for drugs that were paid less due to the 340B policy from CY 2018 through September 27th of CY 2022. As noted previously, the estimated total amount required to remedy providers is $10.6 billion, which includes the $1.6 billion that has already been paid through 340B drug claims processing and reprocessing that occurred for CY 2022 claims.

We note that, in this final rule, we described our policy to annually reduce OPPS payments for non-drug items and services beginning in CY 2026, by decreasing the OPPS conversion factor by 0.5 percent each year until we have offset the full amount of the additional payments made for non-drug items and services from CY 2018 through CY 2022 due to the increase in the conversion factor in those years in response to the 340B payment policy adjustment. This prospective offset will apply to all OPPS providers, including 340B providers, aside from those OPPS providers explicitly excluded as previously discussed. The overall impact of these prospective reductions is estimated to be minus $6.2 billion in Medicare payments alone over the full span of this proposed offset. The estimated impact of this offset for each calendar year for which the offset is estimated to apply is detailed in Table 2 of this final rule.[34] The impact of this offset on payments to each provider type for each calendar year in which the offset is in effect will be included in the regulatory impact analysis for the applicable annual OPPS rulemaking, beginning for CY 2026. However, we note that generally the impact of that annual 0.5 percent reduction to the OPPS conversion factor on individual providers, as well as categories of providers, will depend on the percentage of their OPPS payments that are conversion factor-based, and in most cases will be a decrease of slightly less than 0.5 percent of overall OPPS payments. Please see Table 4 below for our estimated total impact to the OPPS payments based on the information provided in Table 2.

TABLE 4: ESTIMATED ANNUAL IMPACT TO OPPS SPENDING BASED ON 0.5 PERCENT ADJUSTMENT TO THE CONVERSION FACTOR

	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030	CY 2031
0.5-Percent Payment Reduction Amount (millions)	$351	$369	$387	$407	$427	$448
	CY 2032	**CY 2033**	**CY 2034**	**CY 2035**	**CY 2036**	**CY 2037**
0.5-Percent Payment Reduction Amount (millions)	$471	$494	$519	$545	$572	$600
	CY 2038	**CY 2039**	**CY 2040**	**CY 2041**		
0.5-Percent Payment Reduction Amount (millions)	$631	$662	$696	$188		
			Total Offset:	$7.8 billion		

[34] We note that Table 1 illustrates the prospective reductions of $7.8 billion that represent the reduced Medicare payments as well as reduced cost-sharing paid by the beneficiary. The $6.2 billion of the financial impacts discussed here represents only the Medicare payments over the full span of this offset.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's CY 2023 OPPS/ASC proposed rule will be the number of reviewers of the proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule.

For the purposes of our estimate, we assume that each reviewer reads 100 percent of the rule. We welcomed any public comments on the approach in estimating the number of entities that would review the proposed rule. We did not receive any public comments specific to our solicitation.

Using the mean hourly wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $123.06 per hour, which is double the BLS hourly rate in order to account for fringe benefits and other indirect costs in addition to the hourly wage itself.[35] Assuming an average reading speed, we estimate that it would take approximately 3 hours for the staff to review this final rule. For each entity that reviews the rule, the estimated cost is $369.18 (3 hours × $123.06). Therefore, we estimate that the total cost of reviewing this regulation is $608,778 ($369.18 × 1,649). We received 1,649 comments on the proposed rule, which we estimate to be equivalent to the estimated number of reviewers.

[35] *https://www.bls.gov/oes/current/oes_nat.htm.*

E. Alternatives Considered

As also discussed in section II.A above, we evaluated several options to determine which remedy would best achieve the objectives of unwinding the unlawful 340B Payment Policy while making certain OPPS providers as close to whole as is administratively feasible.

For example, we considered making additional payments to affected 340B covered entity hospitals for 340B-acquired drugs from CY 2018 through September 27th of CY 2022 without proposing an adjustment to maintain budget neutrality, which for the reasons stated in section II.A.1 and II.B.2 we determined not to be supported by the statute or the proper exercise of our equitable adjustment or common-law and inherent recoupment authorities. We further considered retrospectively reprocessing all claims from CY 2018 through September 27th of CY 2022, which, for the reasons stated in section II.A.2, we determined not to be operationally feasible and to delay remedy payments to hospitals.

We also considered calculating one-time aggregate payment adjustments for each provider for the CY 2018 through September 27th of CY 2022 time-period, including both additional payments for 340B-acquired drugs and reduced payments for non-drug items and services under sections 1833(t)(2)(E) and (t)(14) of the Act (42 U.S.C. 1395*l*(t)(2)(E) and (t)(14)), along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)). This option would have involved: (1) calculating the total additional payments for each hospital that would have been paid for separately payable non-pass-through 340B-acquired drugs from CY 2018 through September 27th of 2022 in the absence of the 340B Payment Policy; (2) calculating the additional amount each hospital was paid under the OPPS from CY 2018 through CY 2022 for non-drug items and services as a result of the 340B policy; (3) subtracting (2) from (1); and (4) issuing a payment to, or requiring a recoupment from, each hospital for the 5-year period in which the 340B Payment Policy was in effect, which as for the reasons stated in section II.A.3 we determined not to be appropriate in these circumstances. Such an approach would require immediate, and in many cases large, recoupments from the majority of OPPS hospitals and would impose a substantial, immediate burden on these hospitals as well as an uncertain impact on beneficiaries. Given this burden, the financial strain many hospitals experienced during the recent COVID–19 PHE, and the amount of time that has transpired since the original payments for these drugs, items, and services were made, we decided not to propose this option and overly burden these hospitals in this way, making our final option much more generous to OPPS providers.

We refer readers to section II.A of this final rule for additional discussion of all the alternatives we considered, including our reasons for not suggesting them as our final policy.

We are finalizing the prospective offset for reasons previously discussed to begin in CY 2026, which we believe is appropriate rather than other years, as we believe starting this reduction in CY 2026 is responsive to commenter concerns, and will allow CMS time to finalize the appropriate methodology, and then calculate and publish the payment rates derived from this policy in the CY 2026 OPPS/ASC proposed rule, allowing adequate time for impacted parties to assess and prepare for the new payment rates that will be calculated using a reduced conversion factor.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 5 showing the classification of the impact associated with the provisions of this final rule.

BILLING CODE 4120–01–P

TABLE 5: ACCOUNTING STATEMENT

Category	*Estimate*	*Source Citation*		*Year Dollar*
One-time monetized transfers	$9.0 billion	Impact table and impact file, based on the respective 2018 through 2022 claims		CY 2018 through CY 2022
From whom to whom?	Federal Government to affected 340B covered entity hospitals			
Previously monetized transfers (occurring before the finalization of this rule)	$1.6 billion	340 drug claims with dates of service from January 1, 2022, through September 27, 2022, that have already been processed or reprocessed at the default drug payment rate, generally ASP plus 6 percent		CY 2022
From whom to whom?	Federal Government and beneficiaries to affected 340B covered entity hospitals			
Total:	$10.6 billion			
	Transfers*	Year Dollar	Discount Rate	Period Covered
Federal Annualized Monetized ($Millions/Year)	-$465.0	2023	7%	CYs 2026-2041
	-$476.9	2023	3%	CYs 2026-2041
From whom to whom?	Federal Government and beneficiaries to Hospitals and other providers who receive payment under the hospital OPPS (other than new providers).			

*The reduction in annualized monetized transfers is reflective of the aggregate $7.8 billion in future reductions to the OPPS conversion factor based on the parameters of this final rule for calendar years 2026-2041.

BILLING CODE 4120–01–C

We note readers can find provider-level calculations of lump-sum Medicare payments in Addendum AAA to this final rule. If an affected 340B covered hospital entity believes that the payment amount listed for them in Addendum AAA is inaccurate, they can request that CMS review the amount using the technical correction processes described earlier in this rule.

We note that the approximately $9.0 billion of expected transfers in this final rule is the $9.0 billion in expected additional lump sum drug remedy payments associated with this final rule. Some of this amount, $1.6 billion of the total $10.6 billion, has already been remedied through processed or reprocessed 340B drug claims for claims with dates of service from January 1, 2022, through September 27, 2022. We also outline the anticipated $7.8 billion offset to Medicare spending and beneficiary cost-sharing to be implemented through a 0.5 percent reduction to the OPPS conversion factor for certain providers. Table 5 provides the present value of the prospective offset adjustment using discount rates of three and seven percent. We note a commenter referenced the present value of the prospective offset adjustment due to the projected long timeframe. We believe the prospective 0.5 percentage annual reduction in the conversion factor is appropriate because it addresses budget neutrality while also ensuring that the offset was not overly financially burdensome on impacted entities.

G. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small

entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. For details, we refer readers to the Small Business Administration's ''Table of Size Standards'' at *https://www.sba.gov/content/table-small-business-size standards*. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We believe that this threshold will be reached by the requirements in this final rule. As a result, the Secretary has determined that this rule will have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act (42 U.S.C. 1302(b)) requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act (42 U.S.C. 1302(b)), we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule will result in approximately $185 million in remedy payments to 245 small rural hospitals. We note that the estimated payment impact for any category of small entity would depend on the degree to which these entities furnished 340B-acquired drugs.

The analysis, together with the remainder of this final rule, provides a regulatory flexibility analysis and a regulatory impact analysis. We note that the policies contained in this final rule will apply more broadly to OPPS providers and would not specifically focus on small rural hospitals. As a result, the impact on those providers may depend more significantly on their case mix of services as well as the extent to which they furnished 340B-acquired drugs. However, small rural hospitals will experience significant effects from this final rule through the 340B remedy payments if they furnished a significant amount of 340B-acquired drugs and used the ''JG'' modifier.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 602) 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 final rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

We have examined the OPPS and ASC provisions included in this final rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local, or Tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 3 of this final rule, we estimate that payments to impacted governmental hospitals (including State and local governmental hospitals) will increase by approximately $1.8 billion if the policies included in this final rule are finalized. Future adjustments to the OPPS conversion factor to offset the additional non-drug item and service payments made from CY 2018 through CY 2022 due to the 340B Payment Policy will be discussed in the annual rulemaking to which the adjustment will apply.

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

J. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act), the Office of Information and Regulatory Affairs has determined that this action meets the criteria set forth in 5 U.S.C. 804(2).

The analyses we have provided in this section of this final rule, in conjunction with the remainder of this document, demonstrate that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 as amended by Executive Order 14094, the RFA, and section 1102(b) of the Act (42 U.S.C. 1302(b)).

This final rule will affect payments to a small number of small rural hospitals, as well as other classes of hospitals, and some effects may be significant.

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 October 26, 2023.

List of Subjects in 42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 419 as set forth below:

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 1. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395*l*(t), and 1395hh.

■ 2. Section 419.32 is amended by revising paragraph (b)(1)(iv)(B)(*11*) and adding paragraph (b)(1)(iv)(B)(*12*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*11*) For calendar year 2020 through calendar year 2025, a multifactor productivity adjustment (as determined by CMS).

(*12*) Beginning in calendar year 2026, a multifactor productivity adjustment (as determined by CMS), and 0.5 percentage point reduction, except that the 0.5 percentage point reduction shall not apply to hospital outpatient items and services, not including separately payable drugs or biologicals, furnished

by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later. This reduction and associated exception to the reduction will be in effect until the estimated payment reduction reaches $7.769 billion, as further described in each calendar year's rule.

* * * * *

Dated: October 31, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–24407 Filed 11–2–23; 4:15 pm]

BILLING CODE 4120–01–P

Reader Aids

Federal Register

Vol. 88, No. 215

Wednesday, November 8, 2023

CUSTOMER SERVICE AND INFORMATION

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, NOVEMBER

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
10659 74877
10660 75451
10661 75453
10662 75455
10663 75457
10664 75461
10665 75463
10666 76465
10667 75469
10668 75473

Executive Orders:
14110 75191

Administrative Orders:
Notices:
Notice of October 31, 2023 75227
Notice of November 1, 2023 75475
Notice of November 3, 2023 76987

5 CFR

Proposed Rules:
890 75744

7 CFR

205 75394
1260 76097

Proposed Rules:
1000 76143

10 CFR

Proposed Rules:
50 ..... 76143, 76989
51 76143
52 76989
71 76143
430 76510

12 CFR

Proposed Rules:
701 76702
741 76702
746 76702
748 76702
752 76702

13 CFR

130 76625

14 CFR

39 ..... 75477, 76102, 76104, 76107, 76110, 76112, 76114, 76117, 76652
71 ..... 75480, 75481, 75483, 75484, 75486, 75488, 76122, 76655
95 76123

Proposed Rules:
25 ..... 75513, 75517
39 ..... 75520, 76144, 76147, 77044, 77060
61 74908
63 74908
65 74908
71 ..... 75241, 75242, 76150, 76152, 76153, 76155, 76157, 76158
141 74908

15 CFR

744 76128
748 76990
922 75229

16 CFR

Proposed Rules:
1264 74909
1408 76717

17 CFR

232 76896
240 ..... 75100, 75644, 76896
249 75100

Proposed Rules:
232 76282
240 76282

18 CFR

40 74879

21 CFR

73 75490

Proposed Rules:
1 74939
180 75523

24 CFR

891 75230

26 CFR

Proposed Rules:
1 76717
31 76717
54 75744
301 76717

28 CFR

543 76656

Proposed Rules:
345 77064
545 77064

29 CFR

1406 76658
4000 76660
4003 76660
4006 76660
4010 76660
4022 76660
4041A 76660
4043 76660

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List October 10, 2023

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://portalguard.gsa.gov/__*layouts/PG/register.aspx.

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.