



FEDERAL REGISTER

Vol. 89

Thursday,

No. 187

September 26, 2024

Pages 78783–79124

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: 89 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	202-512-1800
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. 89, No. 187

Thursday, September 26, 2024

Agriculture Department

See Forest Service

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 78841–78842

Antitrust Division

NOTICES

Changes under the National Cooperative Research and Production Act:
 Blockchain Security Standards Council, Inc., 78902
 Countering Weapons of Mass Destruction, 78903–78904
 Decentralized Storage Alliance Association, 78904
 Defense Electronics Consortium, 78901–78902
 Integrated Photonics Institute for Manufacturing Innovation Operating Under the Name of the American Institute for Manufacturing Integrated Photonics, 78903
 Maritime Sustainment and Technology Innovation Consortium, 78904
 Medical CBRN Defense Consortium, 78901
 Naval Surface Technology and Innovation Consortium, 78901
 Resilient Infrastructure and Secure Energy Consortium, 78900
 Senior Healthcare Innovation Consortium, 78902
 The Customer Experience Hub, 78902–78903
 The Institute of Electrical and Electronics Engineers, Inc., 78902
 UHD Alliance, 78904–78905
 Undersea Technology Innovation Consortium, 78900

Centers for Disease Control and Prevention

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 78874–78875

Centers for Medicare & Medicaid Services

RULES

Medicaid Program:
 Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 79020–79085

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 78875–78876

Coast Guard

RULES

Drawbridge Operations:
 Milwaukee, Menomonee, and Kinnikinnic Rivers, and South Menomonee and Burnham Canals, 78818–78819
 Safety Zone:
 Commencement Bay, WA, 78819–78821
 Lake Washington, WA, 78821–78823
 Special Local Regulation:
 San Jacinto River, Houston, TX, 78815–78817
NOTICES
 Agency Information Collection Activities; Proposals, Submissions, and Approvals, 78883–78884

Commerce Department

See Foreign-Trade Zones Board

See Industry and Security Bureau

See International Trade Administration

See National Oceanic and Atmospheric Administration

NOTICES

Open Government Plan, 78844–78845

Commodity Futures Trading Commission

RULES

Commodity Pool Operators, Commodity Trading Advisors, and Commodity Pools:
 Qualified Eligible Person Definition, Minimum Disclosure Requirements for Pools and Trading Programs, Permitting Monthly Account Statements for Funds of Funds, 78793–78815

Community Living Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
 Consolidated Program Performance Report, 78878–78879
 Formula Grant Programs, 78877–78878
 Single-Source Supplement Award:
 Alternatives to Guardianship Youth Resource Center Cooperative Agreement, 78876–78877
 Co-Occurring Resource Center for Individuals with Intellectual and/or Developmental Disabilities, 78879–78880

Defense Acquisition Regulations System

RULES

Defense Federal Acquisition Regulation Supplement:
 Assuring Integrity of Overseas Fuel Supplies, 78997–78999
 Data Universal Numbering System to Unique Entity Identifier Transition, 79001–79002
 Modification of Notification of Intent to Transport Supplies by Sea, 78990–78992
 Modification of Prize Authority for Advanced Technology Achievements, 79000–79001
 Preference for United States Vessels in Transporting Supplies by Sea, 78992–78996
 Technical Amendments, 79002

PROPOSED RULES

Defense Federal Acquisition Regulation Supplement:
 Department of Defense Cost or Pricing Data Requirements, 79005–79013
 Preventing Conflicts of Interest for Certain Consulting Services, 79013–79017
 Public Access to Results of Federally Funded Research, 79003–79005

Defense Department

See Defense Acquisition Regulations System

See Engineers Corps

Education Department

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
 Multi-Purpose Financial Information Statement, 78851–78852

Employment and Training Administration**NOTICES**

Hearings, Meetings, Proceedings, etc.:
Workforce Information Advisory Council, 78905–78906

Energy Department

See Federal Energy Regulatory Commission

NOTICES

Importer, Manufacturer or Bulk Manufacturer of Controlled Substances; Application, Registration, etc.:
Golden Pass LNG Terminal LLC, 78852–78854
Privacy Act; Systems of Records, 78854–78858

Engineers Corps**NOTICES**

Environmental Impact Statements; Availability, etc.:
Bayou Lafourche and Lafourche-Jump Waterway, Louisiana, Navigation Channel Project in Lafourche Parish; Withdrawal, 78851

Environmental Protection Agency**PROPOSED RULES**

Air Quality State Implementation Plans; Approvals and Promulgations:
Michigan; St. Clair 2010 Sulfur Dioxide Nonattainment Area, Determination of Attainment by the Attainment Date, 78837–78840

NOTICES

Hearings, Meetings, Proceedings, etc.:
Science Advisory Board Scientific and Technological Achievement Awards Panel, 78868
White House Environmental Justice Advisory Council, 78870–78871
Risk Evaluations for Chemical Substances, 78868–78870

Federal Aviation Administration**RULES**

Airworthiness Directives:
Bell Textron Inc. and Various Restricted Category Helicopters, 78791–78793
Robinson Helicopter Company Helicopters, 78785–78791

PROPOSED RULES

Airspace Designations and Reporting Points:
Auburn, AL, 78832–78834
Brevard, NC, 78831–78832
Victoria, TX, 78834–78835

Airworthiness Directives:

Airbus SAS Airplanes, 78826–78827
The Boeing Company Airplanes, 78827–78831

Federal Communications Commission**RULES**

Location-Based Routing for Wireless 911 Calls, 78823–78825

PROPOSED RULES

Petitions for Reconsideration of Action in Rulemaking Proceeding; Correction, 78840

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 78871–78873

Federal Deposit Insurance Corporation**NOTICES**

Hearings, Meetings, Proceedings, etc.:
Systemic Resolution Advisory Committee, 78873

Federal Election Commission**RULES**

Fraudulent Misrepresentation of Campaign Authority, 78785

PROPOSED RULES

Artificial Intelligence in Campaign Ads, 78826

Federal Emergency Management Agency**NOTICES**

Flood Hazard Determinations, 78886–78894

Federal Energy Regulatory Commission**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 78863–78864
Application:
Eagle Creek Schoolfield, LLC, City of Danville, 78860–78861
Combined Filings, 78862–78863, 78865–78868
Electronic Tariff Filings:
Revised Type of Filing and Validation Error Codes for Testing, 78864–78865
Environmental Assessments; Availability, etc.:
Pacific Gas and Electric Co., 78861
Texas Gas Transmission, LLC and Gulf South Pipeline Co., LLC; Eunice Reliability and Lake Charles Supply Project, 78858
Tower Kleber LP, 78861–78862
Hearings, Meetings, Proceedings, etc.:
Vector Pipeline LP, 78859
Request under Blanket Authorization:
Panhandle Eastern Pipe Line Co., LP, 78865–78866
Tribal Consultation:
Alliance for Tribal Clean Energy, 78859–78860

Federal Highway Administration**NOTICES**

Environmental Impact Statements; Availability, etc.:
Denton and Collin Counties, TX, 78969–78971

Federal Motor Carrier Safety Administration**NOTICES**

Exemption Application:
Qualification of Drivers; Epilepsy and Seizure Disorders, 78973–78975
Qualification of Drivers; Hearing, 78971–78973

Federal Reserve System**NOTICES**

Change in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 78873–78874

Fish and Wildlife Service**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Pollinator Conservation Social Network Analysis Survey, 78894–78895

Food and Drug Administration**PROPOSED RULES**

Food Additive Petition:
PHM Brands; Withdrawal, 78836–78837

NOTICES

Patent Extension Regulatory Review Period:
Osgiveo, 78880–78882

Foreign Assets Control Office**RULES**

Global Magnitsky Sanctions Regulations Web General
License 8, 78815

NOTICES

Sanctions Action, 78975–78985

Foreign-Trade Zones Board**NOTICES**

Authorization of Production Activity:
J.J.C. International Distributors LLC dba Clar Co., Foreign-
Trade Zone 32, Miami, FL, 78845–78846
Proposed Production Activity:
Merck, Sharp and Dohme LLC, Foreign-Trade Zone 49,
Rahway, NJ, 78845

Forest Service**NOTICES**

Environmental Impact Statements; Availability, etc.:
Eldorado and Stanislaus National Forests, CA,
Mokelumne Amador Calaveras Forest Resilience
Project, 78842–78844
Proposed Recreation Fee Sites, 78842

Health and Human Services Department

See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Community Living Administration
See Food and Drug Administration
See National Institutes of Health

NOTICES

Awards Unsolicited Proposal, 78882
Hearings, Meetings, Proceedings, etc.:
2025 Dietary Guidelines Advisory Committee; Scientific
Report, 78883

Homeland Security Department

See Coast Guard
See Federal Emergency Management Agency
See U.S. Customs and Border Protection

RULES

Designation of Qatar for the Visa Waiver Program, 78783–
78785

Industry and Security Bureau**PROPOSED RULES**

End-Use and End-User Based Export Controls, Including
U.S. Persons Activities Controls:
Military and Intelligence End Uses and End Users,
78835–78836
Export Administration Regulations:
Crime Controls and Expansion/Update of United States
Persons Controls; Extension of Comment Period,
78836
Securing the Information and Communications Technology
and Services Supply Chain:
Connected Vehicles, 79088–79123
NOTICES
Denial of Export Privileges:
UTair Aviation JSC, 78846–78848

Interior Department

See Fish and Wildlife Service
See Land Management Bureau
See Reclamation Bureau

Internal Revenue Service**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 78985–78986

International Trade Administration**NOTICES**

Antidumping or Countervailing Duty Investigations, Orders,
or Reviews:
Certain Tungsten Shot from People's Republic of China,
78848–78849

International Trade Commission**NOTICES**

Investigations; Determinations, Modifications, and Rulings,
etc.:
Crystalline Silicon Photovoltaic Cells and Modules from
China, 78900

Justice Department

See Antitrust Division

Labor Department

See Employment and Training Administration
See Occupational Safety and Health Administration

Land Management Bureau**NOTICES**

Requests for Nominations:
Alaska Resource Advisory Council, 78895–78896

National Institutes of Health**NOTICES**

Hearings, Meetings, Proceedings, etc.:
Clinical Center, 78883

National Oceanic and Atmospheric Administration**RULES**

Fisheries of the Exclusive Economic Zone off Alaska:
Pacific Cod by Catcher Vessels Greater Than or Equal to
50 Feet Length Overall Using Hook-and-Line Gear in
the Central Regulatory Area of the Gulf of Alaska,
78825

NOTICES

Hearings, Meetings, Proceedings, etc.:
Fisheries of the Gulf of Mexico; Southeast Data,
Assessment, and Review, 78850–78851
Gulf of Mexico Fishery Management Council, 78849
National Integrated Drought Information System
Executive Council, 78849–78850

National Science Foundation**NOTICES**

Request for Information:
National Plan for Cyber-Physical Systems Resilience,
78915–78916

Neighborhood Reinvestment Corporation**NOTICES**

Meetings; Sunshine Act, 78916

Nuclear Regulatory Commission**NOTICES**

Guidance:
Contamination Control, Radiological Survey, and Dose
Modeling Considerations to Support License
Termination at Sites with Environmental Discrete
Radioactive Particle Contamination, 78917–78918

Hearings, Meetings, Proceedings, etc.:

Accelerating Deployment of Versatile, Advanced Nuclear
for Clean Energy Act, 78916–78917

Occupational Safety and Health Administration

NOTICES

Grant of Permanent Variance:

Ballard Marine Construction Lower Olentangy Tunnel
Project, 78906–78915

Pension Benefit Guaranty Corporation

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Historical Pension Plan Tracing Service Intake
Information, 78918–78919

Reclamation Bureau

NOTICES

Privacy Act; Systems of Records, 78896–78900

Securities and Exchange Commission

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 78919–78920, 78929

Joint Industry Plan:

Consolidated Equity Market Data, 78950

Self-Regulatory Organizations; Proposed Rule Changes:
Cboe Exchange, Inc., 78950–78955

Financial Industry Regulatory Authority, Inc., 78930–
78942

MIAx PEARL, LLC, 78920–78926

Municipal Securities Rulemaking Board, 78955–78967

Nasdaq ISE, LLC, 78928–78929, 78942–78947

Nasdaq PHLX LLC, 78928

New York Stock Exchange LLC, 78926–78928, 78949–
78950

NYSE Arca, Inc., 78948–78949

State Department

NOTICES

Hearings, Meetings, Proceedings, etc.:

International Information and Communications Policy
Division Stakeholder Briefing, 78967

Surface Transportation Board

NOTICES

Quarterly Rail Cost Adjustment Factor, 78967

Susquehanna River Basin Commission

NOTICES

Hearings, Meetings, Proceedings, etc.:

Actions Taken, 78968–78969

Transportation Department

See Federal Aviation Administration

See Federal Highway Administration

See Federal Motor Carrier Safety Administration

NOTICES

Hearings, Meetings, Proceedings, etc.:

Transforming Transportation Advisory Committee, 78975

Treasury Department

See Foreign Assets Control Office

See Internal Revenue Service

U.S. Customs and Border Protection

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Biometric Identity, 78884–78886

Veterans Affairs Department

NOTICES

Assessment of the Scientific Literature and Historical

Claims Data Regarding Exposure to Per- and

Polyfluoroalkyl Substance and Kidney Cancer, 78986–
78987

Separate Parts In This Issue

Part II

Defense Department, Defense Acquisition Regulations
System, 78990–79017

Part III

Health and Human Services Department, Centers for
Medicare & Medicaid Services, 79020–79085

Part IV

Commerce Department, Industry and Security Bureau,
79088–79123

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.

8 CFR	212 (2 documents)	79005, 79013
217	78783	
11 CFR	214	79005
110	78785	215
Proposed Rules:	235	79003
112	78826	237
14 CFR		79013
39 (2 documents)	78826, 78827	252 (3 documents)
		79005, 79013
Proposed Rules:		50 CFR
39 (2 documents)	78785, 78791	679
71 (3 documents)	78831, 78832, 78834	78825
15 CFR		
Proposed Rules:		
730	78835	
732	78835	
734	78835	
736 (2 documents)	78835, 78836	
740	78835	
744 (2 documents)	78835, 78836	
774	78836	
791	79088	
17 CFR		
1	78793	
3	78793	
4	78793	
30	78793	
43	78793	
75	78793	
21 CFR		
Proposed Rules:		
173	78836	
31 CFR		
583	78815	
33 CFR		
100	78815	
117	78818	
165 (2 documents)	78819, 78821	
40 CFR		
Proposed Rules:		
52	78837	
42 CFR		
433	79020	
438	79020	
447	79020	
47 CFR		
9	78823	
Proposed Rules:		
54	78840	
48 CFR		
201	79002	
204 (3 documents)	78990, 79001, 79002	
206	79000	
212 (2 documents)	78990, 78997	
215	78997	
217	79001	
225	78997	
242	78992	
247 (2 documents)	78990, 78992	
252 (3 documents)	78990, 78992, 78997	
Proposed Rules:		
209	79013	

Rules and Regulations

Federal Register

Vol. 89, No. 187

Thursday, September 26, 2024

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

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

DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 217

Designation of Qatar for the Visa Waiver Program

AGENCY: Office of the Secretary, Department of Homeland Security (DHS).

ACTION: Final rule; technical amendment.

SUMMARY: Eligible citizens, nationals, and passport holders from designated Visa Waiver Program countries may apply for admission to the United States at U.S. ports of entry as nonimmigrant noncitizens for a period of ninety days or less for business or pleasure without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission under applicable statutory and regulatory requirements. On September 20, 2024, the Secretary of Homeland Security, in consultation with the Secretary of State, designated Qatar as a country that is eligible to participate in the Visa Waiver Program, effective September 24, 2024. Accordingly, this rule updates the list of countries designated for participation in the Visa Waiver Program by adding Qatar.

DATES: This final rule is effective on September 26, 2024. The Secretary's designation is effective on September 24, 2024. The designation will be implemented on December 1, 2024.

FOR FURTHER INFORMATION CONTACT: Anjum K. Agarwala, Department of Homeland Security, Visa Waiver Program Office, (202) 790-5207.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Visa Waiver Program

Pursuant to section 217 of the Immigration and Nationality Act (INA), 8 U.S.C. 1187, the Secretary of Homeland Security (the Secretary), in

consultation with the Secretary of State, may designate certain countries as Visa Waiver Program (VWP) countries¹ if certain requirements are met. Those requirements include: (1) a U.S. Government determination that the country meets the applicable statutory requirement with respect to nonimmigrant visitor visa refusals for nationals of the country during the previous full fiscal year; (2) a U.S. Government determination that the country extends or agrees to extend reciprocal privileges to citizens and nationals of the United States; (3) an official certification that it issues machine-readable, electronic passports that comply with internationally accepted standards; (4) a U.S. Government determination that the country's designation would not negatively affect U.S. law enforcement and security interests; (5) an agreement with the United States to report, or make available through other designated means, to the U.S. Government information about the theft or loss of passports; (6) a U.S. Government determination that the government accepts for repatriation any citizen, former citizen, or national not later than three weeks after the issuance of a final executable order of removal; and (7) an agreement with the United States to share information regarding whether citizens or nationals of the country represent a threat to the security or welfare of the United States or its citizens.

The INA also sets forth requirements for continued eligibility and, where appropriate, probation and/or termination of program countries.

Prior to this final rule, the designated countries in the VWP were Andorra, Australia, Austria, Belgium, Brunei, Chile, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, New

Zealand, Norway, Poland, Portugal, Republic of Korea, San Marino, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan,² and the United Kingdom.³ See 8 CFR 217.2(a).

Eligible citizens and nationals of VWP countries may apply for admission to the United States at U.S. ports of entry as nonimmigrant visitors for a period of ninety days or less for business or pleasure without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission under applicable statutory and regulatory requirements. To travel to the United States under the VWP, any person who is not a citizen or national of the United States (hereinafter a "noncitizen") must satisfy the following:

- (1) be seeking admission as a nonimmigrant visitor for business or pleasure for ninety days or less;
- (2) be a national of a program country;
- (3) present a machine-readable, electronic passport issued by a designated VWP participant country to the air or vessel carrier before departure;
- (4) execute the required immigration forms;
- (5) if arriving by air or sea, arrive on an authorized carrier;
- (6) not represent a threat to the welfare, health, safety, or security of the United States;
- (7) have not violated U.S. immigration law during any previous admission under the VWP;
- (8) possess a round-trip ticket, unless exempted by statute or federal regulation;
- (9) the identity of the noncitizen has been checked to uncover any grounds on which the noncitizen may be inadmissible to the United States, and no such ground has been found;
- (10) certain aircraft operators, as provided by statute and regulation, must electronically transmit information about the noncitizen passenger;

¹ All references to "country" or "countries" in the laws authorizing the Visa Waiver Program are read to include Taiwan. See Taiwan Relations Act of 1979, Public Law 96-8, section 4(b)(1) (codified at 22 U.S.C. 3303(b)(1)) (providing that "[w]henver the laws of the United States refer or relate to foreign countries, nations, states, governments, or similar entities, such terms shall include and such laws shall apply with respect to Taiwan"). This is consistent with the United States' one-China policy, under which the United States has maintained unofficial relations with Taiwan since 1979.

² Taiwan refers only to individuals who have unrestricted right of permanent abode on Taiwan and are in possession of an electronic passport bearing a personal identification (household registration) number.

³ The United Kingdom refers only to British citizens who have the unrestricted right of permanent abode in the United Kingdom (England, Scotland, Wales, Northern Ireland, the Channel Islands, and the Isle of Man); it does not refer to British overseas citizens, British dependent territories' citizens, or citizens of British Commonwealth countries.

(11) obtain an approved travel authorization via the Electronic System for Travel Authorization (ESTA). For more information about the ESTA, please see 8 CFR 217.5 (regulation effective July 8, 2015), 80 FR 32267 (June 8, 2015), 75 FR 47701 (Aug. 9, 2010);

(12) has not been present, at any time on or after March 1, 2011, in Iraq, Syria, a country that is designated by the Secretary of State as a state-sponsor of terrorism, or a country or area of concern designated by the Secretary of Homeland Security, during the period of those countries' designations, in accordance with 8 U.S.C. 1187(a)(12)(A) & (D), subject to statutorily delineated exemptions or a waiver authorized by the Secretary; and

(13) waive the right to review or appeal a decision regarding admissibility or to contest, other than on the basis of an application for asylum, any action for removal. *See* sections 217(a) and 217(b) of the INA, 8 U.S.C. 1187(a)–(b); *see also* 8 CFR part 217.

B. Designation of Qatar

The Department of Homeland Security, in consultation with the Department of State, has evaluated Qatar for VWP designation to ensure that it meets the requirements set forth in section 217 of the INA. The Secretary has determined that Qatar has satisfied the statutory requirements for initial VWP designation; therefore, the Secretary, in consultation with the Secretary of State, has designated Qatar as a program country.⁴

This final rule adds Qatar to the list of countries authorized to participate in the VWP. Accordingly, no later than December 1, 2024, eligible citizens and nationals of Qatar may apply for admission to the United States at U.S. ports of entry as nonimmigrant visitors for business or pleasure for a period of ninety days or less without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission under applicable statutory and regulatory requirements.

III. Statutory and Regulatory Requirements

A. Administrative Procedure Act

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. The final rule merely lists a country that the Secretary of Homeland

Security, in consultation with the Secretary of State, has designated as a VWP eligible country in accordance with section 217(c) of the INA, 8 U.S.C. 1187(c). This amendment is a technical change to merely update the list of VWP countries. Therefore, notice and comment for this rule is unnecessary and contrary to the public interest because the rule has no substantive impact, is technical in nature, and relates only to management, organization, procedure, and practice.

This final rule is also excluded from the rulemaking provisions of 5 U.S.C. 553 as a foreign affairs function of the United States because it advances the President's foreign policy goals and directly involves relationships between the United States and its noncitizen visitors. Accordingly, DHS is not required to provide public notice and an opportunity to comment before implementing this final rule.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 604(a)), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA), requires an agency to prepare and make available to the public, a regulatory flexibility analysis that describes the effect of a rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions) when the agency was required “to publish a general notice of proposed rulemaking” prior to issuing the final rule. Because this rule is being issued as a final rule without a prior proposal, on the grounds set forth above, a regulatory flexibility analysis is not required under the RFA.

In addition, DHS has considered the impact of this rule on small entities and has determined that this rule will not have a significant economic impact on a substantial number of small entities. The individual noncitizens to whom this rule applies are not small entities as that term is defined in 5 U.S.C. 601(6). Accordingly, there is no change expected in any process as a result of this rule that would have a direct effect, either positive or negative, on a small entity.

C. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions

of the Unfunded Mandates Reform Act of 1995.

D. Executive Order 12866

This amendment does not meet the criteria for a “significant regulatory action” as specified in Executive Order 12866, as amended by Executive Order 14,094.

E. Executive Order 13132

The rule 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. Therefore, in accordance with section 6 of Executive Order 13132, DHS has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988 Civil Justice Reform

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

G. Paperwork Reduction Act

The Department of Homeland Security is modifying the Office of Management and Budget (OMB) Control Number 1651–0111, Arrival and Departure Record, to allow eligible Qatari passport holders to use an ESTA to apply for authorization to travel under the VWP prior to departing for the United States. U.S. Customs and Border Protection (CBP) uses the information to assist in determining if an applicant is eligible for travel under the VWP. The Department is requesting emergency processing of this change to 1651–0111 by October 20, 2024, as the information is essential to the mission of the agency and is needed prior to the expiration of time periods established under the Paperwork Reduction Act of 1995 (PRA). Because of the designation of Qatar for participation in the VWP, the Department is requesting OMB approval of this information collection in accordance with the PRA (44 U.S.C. 3507).

The addition of Qatar to the VWP will result in an estimated annual increase to information collection 1651–0111 of 12,000 responses and 6,500 burden hours. The total burden hours for ESTA, including Qatar, is as follows:

Estimated annual reporting burden: 3,412,500 hours.

Estimated number of respondents: 15,042,000 respondents.

Estimated average annual burden per respondent: 15 minutes.

⁴ The Secretary of State nominated Qatar for participation in the VWP on September 16, 2024.

List of Subjects in 8 CFR Part 217

Air carriers, Aliens, Maritime carriers, Passports and visas.

Amendments to the Regulations

For the reasons stated in the preamble, DHS amends part 217 of title 8 of the Code of Federal Regulations (8 CFR part 217) as set forth below.

PART 217—VISA WAIVER PROGRAM

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 8 U.S.C. 1103, 1187; 8 CFR part 2.

■ 2. In § 217.2(a), revise the definition of “Designated country” to read as follows:

§ 217.2 Eligibility.

(a) * * *

Designated country refers to Andorra, Australia, Austria, Belgium, Brunei, Chile, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Republic of Korea, San Marino, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, and the United Kingdom. The United Kingdom refers only to British citizens who have the unrestricted right of permanent abode in the United Kingdom (England, Scotland, Wales, Northern Ireland, the Channel Islands, and the Isle of Man); it does not refer to British overseas citizens, British dependent territories’ citizens, or citizens of British Commonwealth countries. Taiwan refers only to individuals who have unrestricted right of permanent abode on Taiwan and are in possession of an electronic passport bearing a personal identification (household registration) number.

* * * * *

Alejandro N. Mayorkas,
Secretary.

[FR Doc. 2024–22050 Filed 9–25–24; 8:45 am]

BILLING CODE 9110–9M–P

FEDERAL ELECTION COMMISSION**11 CFR Part 110**

[Notice 2024–24]

Fraudulent Misrepresentation of Campaign Authority

AGENCY: Federal Election Commission.

ACTION: Interpretive rule.

SUMMARY: The Federal Election Commission is issuing guidance on the fraudulent misrepresentation of campaign authority.

DATES: This interpretive rule is effective September 26, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Robert M. Knop, Assistant General Counsel, or Ms. Jennifer Waldman, Attorney, 1050 First Street NE, Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Federal Election Campaign Act (“FECA” or “Act”) prohibits the fraudulent misrepresentation of campaign authority. It does so in two ways: (1) by barring Federal candidates or their agents from fraudulently misrepresenting themselves or organizations under their control as “speaking or writing or otherwise acting for or on behalf of any other candidate or political party or employee or agent thereof on a matter which is damaging to such other candidate or political party or employee or agent thereof” or “willfully and knowingly” participating in or conspiring to do so; and (2) by barring any person from “fraudulently misrepresent[ing]” themselves “as speaking, writing, or otherwise acting for or on behalf of any candidate or political party or employee or agent thereof for the purpose of soliciting contributions or donations” or “willfully and knowingly” participating in or conspiring to do so. 52 U.S.C. 30124; *see also* 11 CFR 110.16.

It has been suggested that this statute may have a specific application in light of new developments in technology, especially content generated with the assistance of artificial intelligence (“AI”). For this reason, the Commission is issuing this guidance to clarify that 52 U.S.C. 30124 and 11 CFR 110.16 apply irrespective of the technology used to conduct fraudulent misrepresentation.

For purposes of 52 U.S.C. 30124, it does not matter whether a regulated person uses any particular form of technology, including AI, in order to “fraudulently misrepresent himself or any committee or organization under his control as speaking or writing or otherwise acting for or on behalf” of another “candidate or political party or employee or agent” or to engage in the “[f]raudulent solicitation of funds” by “misrepresent[ing] the person as speaking, writing, or otherwise acting for or on behalf of any candidate or political party or employee or agent thereof for the purpose of soliciting contributions or donations.” 52 U.S.C. 30124(a)–(b). The legal question is whether the actor fraudulently holds

himself or herself out as “acting for or on behalf of any other candidate or political party or employee or agent thereof.” *Id.* This fraud may be accomplished using AI-assisted media, forged signatures, physically altered documents or media, false statements, or any other means. The statute, and the Commission’s implementing regulation, is technology neutral.

The Commission believes that this interpretation of its statute and attendant regulation will clarify the scope of 52 U.S.C. 30124 in connection with evolving technology, including AI-assisted media and future developments that remain unknown and unpredictable.

This interpretive rule announces the general course of action that the Commission intends to follow. This interpretive rule does not constitute an agency action requiring notice of proposed rulemaking, opportunities for public participation, prior publication, or delay in effective date under 5 U.S.C. 533. It does not bind the Commission or any members of the general public, nor does it create or remove any rights, duties, or obligations. The provisions of the Regulatory Flexibility Act, which apply when notice and comment are required by the Administrative Procedure Act or other relevant statute, do not apply here. *See* 5 U.S.C. 603(a).

Dated: September 20, 2024.

On behalf of the Commission,
Sean J. Cooksey,
Chairman, Federal Election Commission.

[FR Doc. 2024–21983 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2024–0237; Project Identifier AD–2023–00491–R; Amendment 39–22853; AD 2024–19–11]

RIN 2120–AA64

Airworthiness Directives; Robinson Helicopter Company Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Robinson Helicopter Company Model R44 and R44 II helicopters. This AD was prompted by reports of a fractured clutch shaft forward yoke (yoke) on the main rotor (M/R) drive due to fatigue cracking. This AD requires visually

inspecting a certain part-numbered flex plate assembly (flex plate) and certain part-numbered yokes, including each flex plate bolt, and depending on the inspection results, removing an affected part from service and replacing an affected part with an airworthy part. This AD also requires removing a certain part-numbered yoke from service after accumulating a certain number of hours time-in-service (TIS) or a certain number of years, or as an alternative to removing the part from service, performing a 10× or higher power magnification visual inspection and, if needed, a magnetic particle inspection. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 31, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2024–0237; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Related Material: For Robinson material identified in this AD, contact Robinson Helicopter Company, Technical Support Department, 2901 Airport Drive, Torrance, CA 90505; phone: (310) 539–0508; fax: (310) 539–5198; email: ts1@robinsonheli.com; or at [robinsonheli.com](https://www.robinsonheli.com).

FOR FURTHER INFORMATION CONTACT: Eric Moreland, Aviation Safety Engineer, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712; phone: (562) 627–5364; email: Eric.R.Moreland@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

After receiving a report of a failed yoke in the M/R drive system, the FAA issued Special Airworthiness Information Bulletin AIR–22–08, dated April 11, 2022 (SAIB) to remind owners and operators of any Robinson Helicopter Company Model R44 helicopters of the importance of adhering to existing inspection procedures in the applicable operating handbooks and maintenance manuals. According to Robinson Helicopter Company, the yoke had fractured due to fatigue cracking and improper torque at the bolt hole and the yoke cross-section. After the FAA issued the SAIB, Robinson Helicopter Company reported

an additional incident on a Model R44 helicopter where the yoke was fractured and separated from the drive train, again due to fatigue cracks and improper torquing.

Accordingly, the FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Robinson Helicopter Company Model R44 and R44 II helicopters. The NPRM published in the **Federal Register** on February 28, 2024 (89 FR 14596). In the NPRM, the FAA proposed to require visually inspecting a certain part-numbered flex plate for any loose fasteners, cracks, fretting, corrosion, wear, and to ensure that the washers are bonded to both sides of the flex plate arms and depending on the inspection results, removing the flex plate from service and replacing it with an airworthy flex plate.

In the NPRM, the FAA also proposed to require visually inspecting certain part-numbered yokes for any cracks, corrosion, and fretting, and depending on the inspection results, removing the yoke from service and replacing it with an airworthy yoke. Additionally, the FAA proposed to require visually inspecting each yoke bolt for a torque stripe, loose fastener, loose nut, and to determine if a certain part-numbered nut and palnut are installed. If there are any missing torque stripes, loose fasteners, loose nuts, or if certain nuts or palnuts are not installed, the FAA proposed to require removing the associated yoke from service and replacing it with an airworthy yoke.

Additionally in the NPRM, the FAA proposed to require removing from service certain part-numbered yokes that have accumulated more than 12 years or 2,200 total hours TIS, whichever occurs first since first installation on any helicopter, and replacing them with a certain-part-numbered yoke that has accumulated less than 2,200 total hours TIS or 12 years, whichever occurs first since first installation on any helicopter. As an alternative to replacing any yoke that has accumulated more than 12 years or 2,200 total hours TIS since first installation on a helicopter, the FAA proposed to allow removing paint from the yoke and using 10× or higher power magnifying glass to inspect for any crack, seam, lap, shut, missing cadmium plating, or any flaw which is open to the surface, and depending on the inspection results, removing the yoke from service and replacing it with an airworthy yoke. If the yoke is not replaced as a result of the alternate inspection, the FAA proposed to require performing a magnetic particle inspection of the yoke for any crack,

seam, lap, shut, or any flaw which is open to the surface, and depending on the inspection results, removing the yoke from service and replacing with an airworthy yoke.

Finally, if the yoke is replaced as a result of the actions required by the NPRM, the FAA proposed to require torquing each bolt, nut, and palnut using the torque value information in Appendix 1 to the proposed AD. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from two commenters. The following presents the comments received on the NPRM and the FAA's response to each comment.

Comment Supporting the NPRM

One individual commenter supported the NPRM without change.

Comments Requesting Changes to the Required Actions

Request: Robinson Helicopter Company stated the 2,200 hours TIS requirement to replace the affected part or to perform the magnetic particle inspection in the proposed AD corresponds with the engine overhaul, service life limit, and interval for additional maintenance. However, Robinson Helicopter Company stated for Model R44 Cadet helicopters, the hours TIS requirement to replace the affected part or to perform the magnetic particle inspection is a 2,400 hours TIS requirement because of that model's more restrictive operating limitations on maximum takeoff weight and engine power. Therefore, Robinson Helicopter Company requested the FAA increase the hours TIS interval for the replacement of the affected part or the magnetic particle inspection to 2,400 hours TIS for Model R44 Cadet helicopters to allow the operator to coordinate the airworthiness directive requirements with other mandatory maintenance requirements.

FAA Response: The FAA partially agrees with the request. The FAA disagrees with revising this final rule to refer to Model R44 Cadet helicopters because the "Cadet" is not a recognized type-certificated model on the FAA type certificate data sheet. However, the FAA agrees to allow Model R44 helicopters having serial numbers (S/N) 30001 and subsequent (also known as "Cadet" helicopters) to have 2,400 hours TIS to replace an affected part or to perform a magnetic particle inspection. The FAA has revised paragraphs (g)(2) and (3) of

this final rule accordingly to reflect that Model R44 helicopters having S/Ns 30001 and subsequent, on which a yoke replacement as specified in this final rule was not accomplished is required to remove that yoke from service and replace it with an airworthy yoke, prior to the accumulation of 2,400 total hours TIS or within 12 years since first installation, whichever occurs first.

Request: Robinson Helicopter Company stated paragraph (g)(3)(i) of the proposed AD requires the yoke to be replaced if there is any missing cadmium plating. Robinson Helicopter Company stated cadmium plating provides corrosion protection without complete coverage and also can be inadvertently removed during installation and removal of hardware. Robinson Helicopter Company further stated that the requirement to remove the yoke if there is any missing cadmium plating will cause the unnecessary removal of many yokes. Therefore, Robinson Helicopter Company requested the FAA add an exception for cadmium plating and the removal of the yoke from service due to cadmium plating.

FAA Response: The FAA agrees and has revised this AD accordingly by not adopting the inspection and corrective actions associated with cadmium plating proposed in the NPRM.

Request: Robinson Helicopter Company stated paragraph (g)(1)(iii) of the proposed AD requires ensuring that nut part number (P/N) D210–6 and palnut P/N B330–19 are installed. Robinson stated that per type design, only the two bolts on the flex plate assembly have palnut P/N B330–19 installed. Robinson Helicopter Company stated the wording in the proposed AD could cause some Model R44 helicopters to replace a yoke unnecessarily. Robinson Helicopter Company requested the FAA revise paragraph (g)(1)(iii) of the final rule to only apply to bolts shared with the flex plate assembly. Robinson Helicopter Company further stated it is possible some yokes do not have nut P/N D210–6 installed and would therefore also be subject to an unnecessary yoke replacement. Robinson Helicopter Company requested the FAA revise the wording of paragraph (g)(1)(iii) in the final rule to remove the reference to nut P/N D210–6.

FAA Response: The FAA agrees with these requests and revised paragraph (g)(1)(iii) of this AD to clarify that the inspection area is only for the flex plate assembly bolts and to remove any references to nut P/N D210–6.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, any other changes described previously, and a clarification note added to paragraph (g)(1)(i) of this final rule, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Material

The FAA reviewed Robinson Helicopter Company R44 Maintenance Manual and Instructions for Continued Airworthiness, Volume 1, Chapter 2 and Chapter 23, dated September 2023, which specifies procedures for inspecting the yoke and flex plate of the M/R drive, removing paint, applying torque, and performing a magnetic particle inspection. This material also contains the information specified in Appendix 1 to this AD, which specifies torque values, and Figure 1 to paragraph (g)(1) of this AD, which depicts the areas for the flex plate inspection.

Costs of Compliance

The FAA estimates that this AD affects 1,725 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD. Labor costs are estimated at \$85 per work-hour.

Visually inspecting a flex plate will take approximately 0.25 work-hour for an estimated cost of \$21 per helicopter and \$36,225 for the U.S. fleet.

Visually inspecting a yoke, including inspecting each yoke bolt, will take approximately 1.25 work-hours for an estimated cost of \$106 per helicopter and \$182,850 for the U.S. fleet.

Replacing a yoke will take approximately 6 work-hours and parts will cost approximately \$890 for an estimated cost of \$1,400 per helicopter.

Removing paint and inspecting a yoke using 10X or higher power magnifying glass will take approximately 1.5 work-hours for an estimated cost of \$128 per helicopter.

Performing a magnetic particle inspection will take approximately 1.5 work-hours for an estimated cost of \$128 per helicopter.

Applying torque to one bolt, nut, and palnut will take approximately 1 work-hour for an estimated cost of \$85 per hardware set.

If required, replacing a flex plate will take approximately 1 work-hour and parts will cost approximately \$1,240 for

an estimated cost of \$1,325 per helicopter.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will 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 Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–19–11 Robinson Helicopter Company:
Amendment 39–22853; Docket No.
FAA–2024–0237; Project Identifier AD–
2023–00491–R.

(a) Effective Date

This airworthiness directive (AD) is effective October 31, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Robinson Helicopter Company Model R44 and R44 II helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)
Code: 6310, Engine/Transmission coupling.

(e) Unsafe Condition

This AD was prompted by reports of a fractured clutch shaft forward yoke (yoke) on the main rotor (M/R) drive due to fatigue cracking. The FAA is issuing this AD to detect fatigue cracking on the yoke. The unsafe condition, if not addressed, could result in loss of M/R drive and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

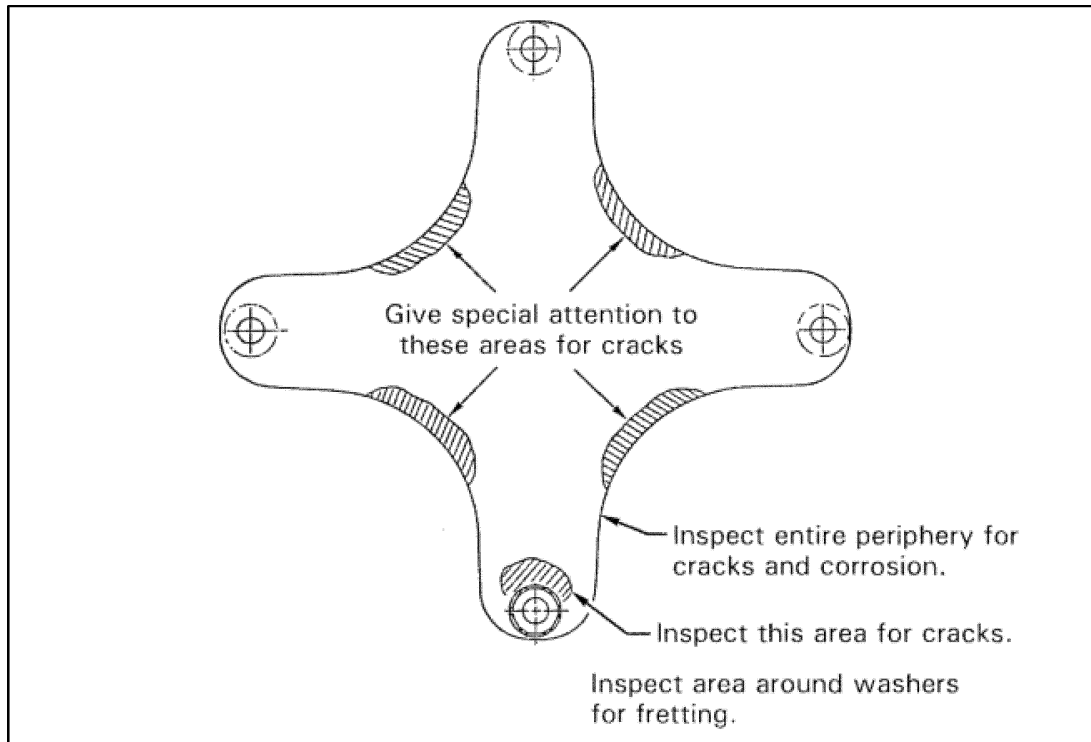
(1) Within 100 hours time-in-service (TIS) after the effective date of this AD, accomplish

the actions required by paragraphs (g)(1)(i) through (iii) of this AD.

(i) Visually inspect forward flex plate assembly (flex plate) part number (P/N) C947–1 for any loose fasteners, cracks, fretting, corrosion, wear, and to ensure that the washers are bonded to both sides of each flex plate arm, in the areas depicted in Figure 1 to paragraph (g)(1)(i) of this AD. If there is any loose fastener (can be moved by hand), crack, fretting, corrosion, or wear that consists of the washers not securely bonded to both sides of each flex plate arm, before further flight, remove the flex plate from service and replace with an airworthy flex plate.

Note 1 to paragraph (g)(1)(i): The flex plate may be installed in order to accomplish the visual inspection.

Figure 1 to Paragraph (g)(1)(i)—Flex Plate Inspection



(ii) Visually inspect yoke P/N C907–1 or C907–2, as applicable to your model helicopter, and yoke P/N C908–1, for any cracks, corrosion, and fretting. If there is any crack, corrosion, or fretting, before further flight, remove the yoke from service and replace it with an airworthy yoke, and torque each newly-installed bolt, nut, and palnut using the torque value information in Appendix 1 to this AD.

(iii) Visually inspect each flex plate bolt for a torque stripe, loose fastener, and a loose nut, and to ensure that palnut P/N B330–19 is installed. If there is a missing torque stripe, loose fastener on any nut (can be moved by hand), or if any nut is loose (nut can be turned by hand), or if palnut P/N B330–19 is not installed, before further flight, remove the associated yoke from service and replace it

with an airworthy yoke, and torque each newly-installed bolt, nut, and palnut using the torque value information in Appendix 1 to this AD.

(2) For Model R44 helicopters having serial number 0002, or 0004 through 9999 inclusive, except not 1140, and R44 II helicopters having serial number 1140 or 10001 through 29999 inclusive on which a yoke replacement as specified in paragraph (g)(1)(ii) or (iii) of this AD was not accomplished: Prior to the accumulation of 2,200 total hours TIS on any yoke P/N C907–1 or C907–2 or within 12 years since first installation of yoke P/N C907–1 or C907–2 on any helicopter, whichever occurs first; or within 100 hours TIS after the effective date of this AD; whichever occurs later, remove that yoke from service and replace it with an

airworthy yoke, and torque each newly-installed bolt, nut, and palnut using the torque value information in Appendix 1 to this AD.

(3) For Model R44 helicopters having serial number 30001 and subsequent, on which a yoke replacement as specified in paragraph (g)(1)(ii) or (iii) of this AD was not accomplished: Prior to the accumulation of 2,400 total hours TIS on any yoke P/N C907–1 or C907–2 or within 12 years since first installation of yoke P/N C907–1 or C907–2 on any helicopter, whichever occurs first; or within 100 hours TIS after the effective date of this AD; whichever occurs later, remove that yoke from service and replace it with an airworthy yoke, and torque each newly-installed bolt, nut, and palnut using the

torque value information in Appendix 1 to this AD.

(4) As an alternative to removing the yoke from service as required by paragraph (g)(2) or (3) of this AD as applicable, remove yoke P/N C907–1 or C907–2, as applicable to your model helicopter, remove the paint on the yoke using Cee-Bee stripper A–292, without using a plastic media abrasive paint stripper, and accomplish paragraphs (g)(4)(i) and (ii) of this AD, as applicable.

(i) Using 10X or higher power magnifying glass, visually inspect the yoke for any crack, seam, lap, shut, and any flaw which is open to the surface. If there is any crack, seam, lap, shut, or flaw, before further flight, remove the yoke from service and replace it with an airworthy yoke, and torque each newly-installed bolt, nut, and palnut using the torque value information in Appendix 1 to this AD.

(ii) If the yoke is not removed from service as a result of the actions required by paragraph (g)(4)(i) of this AD, inspect it for any crack, seam, lap, shut, or any flaw which

is open to the surface by performing a magnetic particle inspection using a method in accordance with FAA-approved procedures. If there is any crack, seam, lap, shut, or flaw, before further flight, remove the yoke from service and replace with an airworthy yoke, and torque each newly-installed bolt, nut, and palnut using the torque value information in Appendix 1 to this AD.

(h) Special Flight Permit

A one-time flight permit may be issued in accordance with 14 CFR 21.197 and 21.199 in order to fly to a maintenance area to perform the required actions in this AD, provided there are no passengers onboard.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, West Certification Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your

request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the West Certification Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *AMOC@faa.gov*.

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

(j) Related Information

For more information about this AD, contact Eric Moreland, Aviation Safety Engineer, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712; phone: (562) 627–5364; email: *Eric.R.Moreland@faa.gov*.

(k) Material Incorporated by Reference

None.

Appendix 1 to AD 2024–19–11

BILLING CODE 4910–13–P

NOTE

1. Torque values are in inch-pounds unless otherwise specified.
2. Torque values include nut self-locking torque.
3. Increase torque values 10% if torqued at bolt head.
4. Wet indicates threads lubricated with A257-9 anti-seize.
5. For elbow and tee fittings which require alignment, torque to indicated value, then tighten to desired position.
6. Tolerance is $\pm 10\%$ unless range is specified.
7. Unless otherwise specified, thread sizes 8-32 and smaller are not used for primary structure and do not require control of torques.

FASTENER SERIES		SIZE	EXAMPLE FASTENER	TORQUE (IN.-LB)
NAS6603 thru NAS6608 Bolts NAS1303 thru NAS1308 Bolts NAS623 Screws NAS1351 & NAS1352 Screws NAS600 thru NAS606 Screws		10-32	NAS6603	50
		1/4-28	NAS6604	120
		5/16-24	NAS6605	240
		3/8-24	NAS6606	350
		7/16-20	NAS6607	665
		1/2-20	NAS6608	995
A142 screws AN3 Bolts AN4 Bolts AN6 Bolts AN8 Bolts	AN502 Screws	10-32	A142-1, -3, -4; AN3	37
	AN503 Screws	1/4-28	AN4	90
	AN509 Screws	3/8-24	AN6	280
	AN525 Screws MS24694 Screws MS27039 Screws	1/2-20	AN8	795
STAMPED NUTS (PALNUTS) Palnuts are to be used only once and replaced with new when removed.		10-32	B330-7 (MS27151-7)	6-15
		1/4-28	B330-13 (MS27151-13)	11-25
		5/16-24	B330-16 (MS27151-16)	20-40
		3/8-24	B330-19 (MS27151-19)	29-60
		7/16-20	B330-21 (MS27151-21)	42-85
		1/2-20	B330-24 (MS27151-24)	54-110
TAPERED PIPE THREADS		1/8-27	See note 5	60
			Straight fittings only	120
		1/4-18	See note 5	85
			Straight fittings only	170
		3/8-18	See note 5	110
			Straight fittings only	220
		1/2-14	See note 5	160
			Straight fittings only	320
ROD END JAM NUTS (AN315 and AN316)		3/4-14	See note 5	230
			Straight fittings only	460
		10-32	AN315-3	15
		1/4-28	AN316-4	40
		5/16-24	AN316-5	80
		3/8-24	AN316-6	110

Issued on September 19, 2024.

Victor Wicklund,

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

[FR Doc. 2024-21921 Filed 9-25-24; 8:45 am]

BILLING CODE 4910-13-C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2024-2319; Project Identifier AD-2024-00498-R; Amendment 39-22859; AD 2024-19-17]

RIN 2120-AA64

Airworthiness Directives; Bell Textron Inc. and Various Restricted Category Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Bell Textron Inc. Model 204B, 205A, 205A-1, 205B, 210, and 212 helicopters and various restricted category helicopters with certain part-numbered tension torsion (TT) straps installed by supplemental type certificate (STC) No. SR03408CH. This AD was prompted by an accident involving failure of a TT strap. This AD requires removing the specified part-numbered TT straps from service and prohibits installing those TT straps. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 11, 2024.

The FAA must receive comments on this AD by November 12, 2024.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA-2024-2319; or in person at Docket Operations between 9 a.m. and

5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT:

Brian Hanley, Aviation Safety Engineer, FAA, 1801 S Airport Road, Wichita, KS 67209; phone: (847) 294-8140; email: *Brian.Hanley@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2024-2319; Project Identifier AD-2024-00498-R” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Brian Hanley, Aviation Safety Engineer, FAA, 1801 S Airport Road, Wichita, KS 67209; phone: (847) 294-8140; email: *Brian.Hanley@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

This AD was prompted by an accident involving a Bell Textron Inc. Model 212 helicopter, which experienced a separation of a main rotor blade from the main rotor head and subsequent impact into terrain shortly after takeoff. Initial investigation determined the TT strap failed at 664 total hours time-in-service (TIS). Investigations into individual wire failure mechanisms are ongoing with early indications suggesting some wires possibly failed in tensile overload and others in fatigue. Bell Textron Inc. Model 204B, 205A, 205A-1, 205B, and 210 helicopters and various restricted category helicopters are also affected by this unsafe condition since the affected TT straps may also be installed on these model helicopters.

This condition, if not addressed, could result in loss of a main rotor blade and subsequent loss of control of the helicopter. The FAA is issuing this AD to address the unsafe condition on these products.

FAA’s Determination

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

AD Requirements

This AD requires removing TT straps part numbers AA-204-310-101-101, AA-204-310-101-101C, AA-204-310-101-103, and AA-204-310-101-103C installed by STC No. SR03408CH from service and prohibits installing those TT straps on any helicopter.

Interim Action

The FAA considers this AD to be an interim action. If final action is later identified, the FAA might consider further rulemaking then.

Justification for Immediate Adoption and Determination of the Effective Date

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

make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because an affected TT strap was involved in an accident in which the TT strap failed, resulting in the main rotor blade detaching from the main rotor head. Failure of an affected TT strap could occur at any time without any previous indications and result in a sudden and catastrophic condition. Thus, an urgent unsafe condition exists and the required actions must be done within 50 hours TIS, a time period of up to two months based on the average flight-hour utilization rates of these helicopters. However, a significant portion of these helicopters in the U.S. fleet are high usage helicopters, which have an increased likelihood of occurrence of a failure and will reach the compliance time within a period of approximately one week based on the average flight-hour utilization rates of these helicopters. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b).

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

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD affects 120 helicopters of U.S. registry. Labor rates are estimated at \$85 per work-hour. Based on these numbers, the FAA estimates that operators may incur the following costs in order to comply with this AD.

Replacing the TT straps (two TT straps per helicopter) will take 10 work-hours and parts will cost \$18,000 for an estimated cost of \$18,850 per helicopter and \$2,262,000 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024-19-17 Bell Textron Inc. and Various Restricted Category Helicopters:
Amendment 39-22859; Docket No.

FAA-2024-2319; Project Identifier AD-2024-00498-R.

(a) Effective Date

This airworthiness directive (AD) is effective October 11, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the helicopters identified in paragraphs (c)(1) and (2) of this AD with tension torsion (TT) straps part-number AA-204-310-101-101, AA-204-310-101-101C, AA-204-310-101-103, or AA-204-310-101-103C installed in accordance with Supplemental Type Certificate No. SR03408CH.

(1) Bell Textron Inc. Model 204B, 205A, 205A-1, 205B, 210, and 212 helicopters, certificated in any category; and

(2) The various restricted category helicopters identified in paragraphs (c)(2)(i) through (xiii) of this AD.

(i) Model 209/AH-1G helicopters; current type certificate holders include, but are not limited to, Attack Logistics LLC.

(ii) Model AH-1S helicopters; current type certificate holders include, but are not limited to, US Helicopter, Inc.

(iii) Model HH-1K helicopters; current type certificate holders include, but are not limited to, Midwest Aerospace TC LLC.

(iv) Model SW205A-1 helicopters; current type certificate holders include, but are not limited to, Southwest Florida Aviation International, Inc.

(v) Model TH-1F helicopters; current type certificate holders include, but are not limited to, Midwest Aerospace TC LLC, Robinson Air Crane, Inc., and Tamarack Helicopters, Inc.

(vi) Model TH-1L helicopters; current type certificate holders include, but are not limited to, Bell Textron Inc., Midwest Aerospace TC LLC, and Overseas Aircraft Support, Inc.

(vii) Model UH-1A helicopters; current type certificate holders include, but are not limited to, Richards Heavylift Helo, Inc.

(viii) Model UH-1B helicopters; current type certificate holders include, but are not limited to, International Helicopters, Inc., Midwest Aerospace TC LLC, Overseas Aircraft Support, Inc., Red Tail Flying Services LLC, Richards Heavylift Helo, Inc., Southwest Florida Aviation International, Inc., and WSH, LLC.

Note 1 to paragraph (c)(2)(viii): Helicopters with an SW204 or SW204HP designation are Southwest Florida Aviation International, Inc., Model UH-1B helicopters.

(ix) Model UH-1E helicopters; current type certificate holders include, but are not limited to, Bell Textron Inc., Midwest Aerospace TC LLC, Overseas Aircraft Support, Inc., Smith Helicopters, and West Coast Fabrications.

(x) Model UH-1F helicopters; current type certificate holders include, but are not limited to, AST, Inc., California Department of Forestry, Midwest Aerospace TC LLC, Robinson Air Crane, Inc., and Tamarack Helicopters, Inc.

(xi) Model UH-1H helicopters; current type certificate holders include, but are not

limited to, Arrow Falcon Exporters Inc., Global Helicopter Technology, Inc., Hagglund Helicopters, LLC, JJASPP Engineering Services, LLC., Midwest Aerospace TC LLC, Northwest Rotorcraft, LLC, Overseas Aircraft Support, Inc., Richards Heavylift Helo, Inc., Southwest Florida Aviation International, Inc., and Tamarack Helicopters, Inc.

Note 2 to paragraph (c)(2)(xi): Helicopters with an SW205 designation are Southwest Florida Aviation International, Inc., Model UH-1H helicopters.

(xii) Model UH-1L helicopters; current type certificate holders include, but are not limited to, Bell Textron Inc., Midwest Aerospace TC LLC, and Overseas Aircraft Support, Inc.

(xiii) Model UH-1P helicopters; current type certificate holders include, but are not limited to, Midwest Aerospace TC LLC and Robinson Air Crane, Inc.

(d) Subject

Joint Aircraft System Component (JASC) Code 6700, Rotorcraft flight control.

(e) Unsafe Condition

This AD was prompted by an accident involving failure of a TT strap, which resulted in the main rotor blade detaching from the main rotor head. The FAA is issuing this AD to address failure of a TT strap. The unsafe condition, if not addressed, could result in loss of a main rotor blade and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Remove the TT straps from service and replace them with airworthy TT straps at the compliance time required by paragraphs (g)(1)(i) or (ii) of this AD, as applicable.

(i) For TT straps that as of the effective date of this AD have accumulated 350 or more total hours time-in-service (TIS) since first installation on any helicopter, within 50 hours TIS after the effective date of this AD.

(ii) For TT straps that as of the effective date of this AD have accumulated less than 350 total hours TIS since first installation on any helicopter, before the TT straps accumulate 400 total hours TIS since first installation on any helicopter.

(2) As of the effective date of this AD, do not install the TT straps identified in the introductory text of paragraph (c) of this AD on any helicopter.

(h) Special Flight Permit

Special flight permits are prohibited.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Central Certification Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the Central Certification

Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: AMOC@faa.gov.

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

(j) Additional Information

For more information about this AD, contact Brian Hanley, Aviation Safety Engineer, FAA, 1801 S Airport Road, Wichita, KS 67209; phone: (847) 294-8140; email: Brian.Hanley@faa.gov.

(k) Material Incorporated by Reference

None.

Issued on September 23, 2024.

Steven W. Thompson,

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

[FR Doc. 2024-22095 Filed 9-23-24; 4:15 pm]

BILLING CODE 4910-13-P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1, 3, 4, 30, 43, and 75

RIN 3038-AF25

Commodity Pool Operators, Commodity Trading Advisors, and Commodity Pools Operated: Updating the ‘Qualified Eligible Person’ Definition; Adding Minimum Disclosure Requirements for Pools and Trading Programs; Permitting Monthly Account Statements for Funds of Funds; Technical Amendments

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (Commission or CFTC) is adopting amendments to certain provisions of its regulations (the Final Rule) that would update the Portfolio Requirement thresholds within the “Qualified Eligible Person” definition; include revisions that are consistent with long-standing Commission exemptive letters addressing the timing of certain pools’ periodic financial reporting; and make several technical amendments related to the structure of the regulations that are the subject of this Final Rule.

DATES:

Effective date: This rule is effective November 25, 2024.

Compliance date: Commodity pool operators (CPOs) and commodity trading advisors (CTAs) must comply with the increased Portfolio

Requirement thresholds in Commission regulation § 4.7(a) by March 26, 2025. The optional monthly account statement reporting schedule for certain § 4.7 pools in Commission regulation § 4.7(b)(3)(iv) is available to CPOs as of the effective date, and compliance is required upon election of that schedule by the CPO.

FOR FURTHER INFORMATION CONTACT:

Amanda L. Olear, Director, 202-418-5283 or aolear@cftc.gov; Pamela M. Geraghty, Acting Deputy Director, 202-418-5634 or pgeraghty@cftc.gov; Elizabeth Groover, Acting Associate Director, 202-418-5985 or egroover@cftc.gov; or Andrew Ruggiero, Special Counsel, 202-418-5712 or aruggiero@cftc.gov; each in the Market Participants Division at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction and Background
- II. The Final Rule
 - A. General Overview of Comments Received
 - B. Minimum QEP Disclosure Requirements Under Commission Regulation § 4.7
 - C. Updating Financial Thresholds in the Portfolio Requirement of the “Qualified Eligible Person” Definition
 - D. Permitting Monthly Account Statements for Certain 4.7 Pools Consistent With Commission Exemptive Letters
 - E. Other Technical Amendments
 - F. Effective and Compliance Dates for the Final Rule
- III. Related Matters
 - A. Regulatory Flexibility Act
 - B. Paperwork Reduction Act
 - C. Cost-Benefit Considerations
 - D. Antitrust Considerations

I. Introduction and Background

As amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act),¹ section 1a(11) of the Commodity Exchange Act (CEA or Act) defines the term “commodity pool operator” as any person engaged in a business that is of the nature of a commodity pool, investment trust, syndicate, or similar form of enterprise, and who, with respect to that commodity pool, solicits, accepts, or receives from others, funds, securities, or property, either directly or through capital contributions, the sale of stock or other forms of securities, or otherwise, for the purpose of trading in commodity interests.² CEA section 1a(10) defines a “commodity pool” as any investment trust, syndicate, or similar form of enterprise operated for the purpose of

¹ Public Law 111-203, 124 Stat. 1376 (2010).

² 7 U.S.C. 1a(11).

trading in commodity interests.³ CEA section 1a(12) defines the term “commodity trading advisor” as any person who, for compensation or profit, engages in the business of advising others, either directly or through publications, writing, or electronic media, as to the value of or the advisability of trading in commodity interests.⁴

Generally, CEA section 4m(1) requires each person whose activities satisfy either the CPO or CTA definition to register as such with the CFTC.⁵ With respect to both CPOs and CTAs, the CEA also authorizes the Commission to include persons within, or exclude them from, such definitions, by rule, regulation, or order, if the Commission determines that such action will effectuate the purposes of the CEA.⁶ In addition to the general registration authority set forth in CEA section 4m(1), CEA section 4n specifically empowers the Commission to impose compliance obligations related to the registration process, recordkeeping, disclosure, and reporting.⁷ Finally, the CEA also gives the Commission authority to make and promulgate such rules and regulations, as in the judgment of the Commission, are reasonably necessary to effectuate the provisions or to accomplish any purposes of the CEA.⁸

Part 4 of the Commission’s regulations specifically governs the operations and activities of CPOs and CTAs.⁹ These regulations establish registration exemptions and definitional exclusions for CPOs and CTAs,¹⁰ and contain detailed regulations that establish the ongoing compliance obligations applicable to registered CPOs and CTAs, which implement the statutory authority granted to the Commission by the CEA with respect to such registrants.¹¹ Specifically, the regulatory compliance requirements facilitate the Commission’s oversight of their activities in the commodity interest markets and promote customer protection through operational

requirements,¹² disclosures,¹³ and regular reporting¹⁴ to a registrant’s pool participants or advisory clients. Commission regulation § 4.7 provides exemptions from certain part 4 compliance requirements regarding disclosure, periodic reporting, and recordkeeping for registered CPOs and CTAs, whose prospective and actual pool participants and/or advisory clients are restricted to individuals and entities considered “Qualified Eligible Persons,” and who claim the desired exemptions, pursuant to paragraph (d) of that section.¹⁵ Since its adoption over thirty years ago, the Commission has occasionally amended Commission regulation § 4.7 to enhance its usability and ensure that it remains fit for purpose.¹⁶

After a careful review of the existing language and structure of Commission regulation § 4.7, and considering the public and regulatory interest of maintaining and modernizing older, but still widely utilized provisions, the Commission approved and published in the **Federal Register** a notice of proposed rulemaking (NPRM or Proposal) comprised of targeted amendments to update the regulation in several ways.¹⁷ The Commission noted in the NPRM that, as of the end of FY 2022, 837 registered CPOs operated approximately 4,304 commodity pools pursuant to claimed Commission regulation § 4.7 exemptions (§ 4.7 pools, and together with CTA programs operated under Commission regulation § 4.7, the § 4.7 pools and trading programs).¹⁸ Relatedly, approximately 865 CTAs claim an exemption under Commission regulation § 4.7 for their trading programs, which the Commission also estimates to number in the tens of thousands. The Commission further stated that, during discussions with CFTC staff, the National Futures

Association (NFA), the registered futures association to whom the Commission has delegated many of its regulatory oversight functions with respect to CPOs and CTAs, predicted that this population of CPOs, CTAs, commodity pools, and trading programs operating pursuant to Commission regulation § 4.7 will only continue to grow in the future.¹⁹ More recent data on the usage of Commission regulation § 4.7 shows this to be the case. As of June 2024, approximately 824 CPOs claim exemptions under Commission regulation § 4.7, with respect to 4,763 § 4.7 pools, and 822 CTAs claim exemptions under Commission regulation § 4.7 with respect to at least 10,000 § 4.7 trading programs.²⁰

In particular, the Commission proposed amendments that sought: (1) to increase the financial thresholds in the Portfolio Requirement of the “Qualified Eligible Person” (QEP) definition in Commission regulation § 4.7(a) to reflect inflation; (2) to require certain minimum disclosures for § 4.7 pools and trading programs operated and offered by CPOs and CTAs; (3) to add a process under Commission regulation § 4.7(b)(3) permitting CPOs to elect an alternative account statement schedule for certain § 4.7 pools consistent with long-standing exemptive letters issued by the Commission;²¹ and (4) to improve the structure and utility of Commission regulation § 4.7 through several technical adjustments (for example, reorganizing the QEP definition, updating cross-references, etc.). After consideration of the public comments received in response to the NPRM, as well as several meetings with

¹⁹ In fact, as of March 31, 2023, there were approximately 1,128 CPOs registered with the Commission, and on average, approximately 5,257 pools were reported via CFTC Form CPO-PQR on a quarterly basis in FY 2022. Assuming there is no material difference in the number of registered CPOs and pools reported between the closings of Q4 2022 and of Q1 2023, NFA and CFTC data show that approximately 69% of registered CPOs operate § 4.7 pools, and approximately 81% of all pools reported on CFTC Form CPO-PQR are § 4.7 pools. After amendments to Form CPO-PQR and Commission regulation § 4.27 adopted in 2020, the Commission accepts NFA Form PQR as substituted compliance for the required completion of its own Form CPO-PQR. See 17 CFR 4.27. Therefore, the data sources for both NFA and CFTC are fundamentally the same, if not identical.

²⁰ With these updated figures, § 4.7 CPOs continue to comprise approximately 69% of all CPOs registered with the Commission, and 4.7 CTAs 66% of all CTAs registered with the Commission, while approximately 86% of all commodity pools operated by a registered CPO are § 4.7 pools.

²¹ Such exemptive letters are routinely drafted by Commission staff in the Market Participants Division (MPD) and constitute an exercise of the authority in Commission regulation §§ 4.12(a) and 140.93. See 17 CFR 4.12(a) and 140.93.

¹² See, e.g., 17 CFR 4.20(c), 4.30(a) (prohibiting the commingling of pool funds with those of any other person and prohibiting CTAs from accepting funds from advisory clients in the CTA’s name, respectively).

¹³ 17 CFR 4.24, 4.25, 4.34, 4.35.

¹⁴ 17 CFR 4.22.

¹⁵ 17 CFR 4.7.

¹⁶ See, e.g., 77 FR 11252 (Feb. 24, 2012) (rescinding the relief from the audit requirement for pool annual reports previously provided under Commission regulation § 4.7(b)(4)); 84 FR 67355 (Dec. 10, 2019).

¹⁷ Commodity Pool Operators, Commodity Trading Advisors, and Commodity Pools: Updating the ‘Qualified Eligible Person’ Definition; Adding Minimum Disclosure Requirements for Pools and Trading Programs; Permitting Monthly Account Statements for Funds of Funds; Technical Amendments, 88 FR 70852 (Oct 12, 2023) (NPRM or Proposal).

¹⁸ These numbers were drawn from data in National Futures Association Form PQR filings for Q4 2022.

³ 7 U.S.C. 1a(10).

⁴ 7 U.S.C. 1a(12).

⁵ 7 U.S.C. 6m(1) (It shall be unlawful for any CTA or CPO, unless registered under this chapter, to make use of the mails or any means or instrumentality of interstate commerce with his business as such CTA or CPO). See also 17 CFR 3.10.

⁶ 7 U.S.C. 1a(11)(B); 7 U.S.C. 1a(12)(B)–(C).

⁷ 7 U.S.C. 6n.

⁸ 7 U.S.C. 8a(5).

⁹ 17 CFR part 4.

¹⁰ See 7 U.S.C. 6n; 17 CFR 4.5, 4.6, 4.13, 4.14.

¹¹ See, generally, 17 CFR 4.20 through 4.26, 4.30 through 4.36.

interested members of the public,²² the Commission has determined to finalize portions of the Proposal, while continuing to consider the remaining proposed amendments and alternative approaches offered by commenters.

II. The Final Rule

A. General Overview of Comments Received

The Commission requested comment on all aspects of the NPRM and also solicited comment through specific, targeted questions about each of the individual proposed amendments.²³ The Commission received eight comment letters in response to the Proposal, including six from industry associations, one from NFA, and one from a law firm that frequently represents CPOs and CTAs utilizing Commission regulation § 4.7 exemptions.²⁴ Overall, comments on the Proposal were mixed, depending on which amendment was being discussed. With respect to the Portfolio Requirement updates, commenters largely agreed with the necessity of the proposed increases to account for

inflation and were, for the most part, supportive of that proposed amendment. With respect to adding minimum disclosure requirements to Commission regulation § 4.7 for all QEP pool participants and advisory clients, commenters disagreed with the amendments as proposed and made several suggestions seeking to narrow or eliminate the proposed disclosures. The proposed amendment designed to align Commission regulation § 4.7 with Commission exemptive letters that permit the distribution of monthly, rather than quarterly, account statements for certain § 4.7 pools received unanimous support and will consequently be adopted as proposed by the Final Rule amendments. The following sections discuss the proposed amendments in more detail, the comments the Commission received from the public, as well as the terms of the Final Rule being adopted herein.

B. Minimum QEP Disclosure Requirements Under Commission Regulation § 4.7

1. The Proposal

Currently, Commission regulation § 4.7 provides exemptions from the broader part 4 compliance requirements for CPOs with respect to pools offered solely to QEPs, and for CTAs advising or managing the accounts of QEPs, including those regulations requiring disclosure of general and performance information about a pool or trading program. Specifically, Commission regulation § 4.7(b)(2) provides an exemption for CPOs with respect to their pools offered solely to QEPs regarding: (1) the requirement to deliver a disclosure document in Commission regulation § 4.21; (2) the general disclosures required by Commission regulation § 4.24; (3) the performance disclosures required by Commission regulation § 4.25; and (4) the use and amendment requirements in Commission regulation § 4.26; so long as the CPO provides a form statement on the cover page of any offering memorandum it chooses to distribute to its prospective pool participants (or near the signature line of the pool's subscription agreement, if its CPO chooses not to distribute an offering memorandum).²⁵ Similarly, Commission regulation § 4.7(c)(1)

provides an exemption for CTAs with respect to their trading programs offered to QEPs regarding: (1) the requirement to deliver a disclosure document in Commission regulation § 4.31; (2) the general disclosures required by Commission regulation § 4.34; (3) the performance disclosures required by Commission regulation § 4.35; and (4) the use and amendment requirements in Commission regulation § 4.36; provided that the CTA includes a form statement on the cover page of any brochure or disclosure statement it chooses to distribute to its prospective advisory clients (or near the signature line of the advisory agreement, if the CTA chooses not to distribute a brochure or disclosure statement).²⁶ CPOs and CTAs claiming these exemptions²⁷ are not required to deliver or disseminate any offering memoranda, brochures, or disclosure statements to their prospective QEP pool participants or advisory clients. Rather, these CPOs and CTAs are only required to ensure that any information or disclosures they elect to provide to QEPs (QEP Disclosures), include all disclosures necessary to make the information contained therein, in the context in which it is furnished, not misleading.²⁸

Under the Proposal, the Commission proposed to amend the disclosure relief provided by current Commission regulation § 4.7(b)(2)(i) and (ii) to require CPOs to deliver a set of disclosures to their § 4.7 pools' prospective QEP participants.²⁹ The proposed disclosure requirements included descriptions of the § 4.7 pool's: (i) principal risk factors; (ii) investment program; (iii) use of proceeds; (iv) custodians; (v) fees and expenses; (vi) conflicts of interest; and (vii) targeted past performance information. Generally, the Commission proposed to establish these minimum disclosure requirements by rescinding or narrowing certain of the existing exemptions in Commission regulation § 4.7, including those from Commission regulation §§ 4.21, 4.24, and 4.25.³⁰ Proposed Commission regulation § 4.7(b)(2)(i)(F) included the requirement that QEP Disclosures provide all disclosures necessary to make the information contained therein,

²² All comments on the NPRM, including notices of *ex parte* meetings discussing this rulemaking, are available at <https://comments.cftc.gov/PublicComments/CommentList.aspx?id=7443>.

²³ See, e.g., Proposal, 88 FR 70855 (requesting comment on the proposed Portfolio Requirement increases, as well as posing specific questions for commenters to address).

²⁴ Comment Letter from the Securities Industry and Financial Markets Association Asset Management Group (Dec. 11, 2023), available at [https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73190&SearchText=\(SIFMA AMG Letter\)](https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73190&SearchText=(SIFMA%20AMG%20Letter)); Comment Letter from the Investment Advisers Association (Dec. 11, 2023), available at [https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73192&SearchText=\(IAA Letter\)](https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73192&SearchText=(IAA%20Letter)); Comment Letter from the Alternative Investment Management Association Limited (Dec. 11, 2023), available at [https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73193&SearchText=\(AIMA Letter\)](https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73193&SearchText=(AIMA%20Letter)); Comment Letter from the Managed Funds Association (Dec. 11, 2023), available at [https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73194&SearchText=\(MFA Letter\)](https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73194&SearchText=(MFA%20Letter)); Comment Letter from the Investment Company Institute (Dec. 11, 2023), available at [https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73195&SearchText=\(ICI Letter\)](https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73195&SearchText=(ICI%20Letter)); Comment Letter from the National Futures Association (Dec. 11, 2023), available at [https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73191&SearchText=\(NFA Letter\)](https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73191&SearchText=(NFA%20Letter)); and Comment Letter from Dechert, LLP (Dec. 11, 2023), available at [https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73196&SearchText=\(Dechert Letter\)](https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73196&SearchText=(Dechert%20Letter)). One commenter also submitted a supplemental comment letter after the closing of the NPRM's public comment period. See Supplemental Comment Letter from the Managed Funds Association (Jun. 26, 2024), available at [https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73840&SearchText=\(MFA Comment Letter II\)](https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=73840&SearchText=(MFA%20Comment%20Letter%20II)). The NPRM's complete comment file is available at <https://comments.cftc.gov/PublicComments/CommentList.aspx?id=7443>.

²⁵ 17 CFR 4.7(b)(2) (providing an exemption from the specific requirements of Commission regulation §§ 4.21, 4.24, 4.25, and 4.26 with respect to each § 4.7 pool). The prescribed "form statement" indicates that the CPO's offering memorandum has not been, nor is it required to be, filed with the Commission, and that the CFTC has not reviewed or approved such offerings or any related offering memoranda for the § 4.7 pool. *Id.*

²⁶ 17 CFR 4.7(c)(1) (providing an exemption from the specific requirements of Commission regulation §§ 4.31, 4.34, 4.35, and 4.36 with respect to an offered § 4.7 trading program). The prescribed "form statement" indicates the CTA's brochure has not been, nor is it required to be, filed with the Commission, and that the CFTC has not reviewed or approved such trading program or brochure. *Id.*

²⁷ See 17 CFR 4.7(d).

²⁸ 17 CFR 4.7(b)(2); 17 CFR 4.7(c)(1).

²⁹ Proposal, 88 FR 70859.

³⁰ *Id.*

in the context in which it is furnished, not misleading, and Proposed Commission regulation § 4.7(b)(2)(i)(G) continued to require a form disclaimer like that currently required by Commission regulation § 4.7(b)(2)(i).

As a consequence of requiring these minimum disclosures for § 4.7 pools, the Commission also proposed to update corresponding recordkeeping, and use and amendment requirements. Specifically, the Commission proposed to amend Commission regulation § 4.7(b)(5) to require that CPOs maintain such QEP Disclosures among the other books and records of their § 4.7 pools, and make them available, upon request, to the Commission, NFA, and the U.S. Department of Justice, in accordance with Commission regulation § 1.31.³¹ Additionally, the Commission proposed to narrow the exemption from Commission regulation § 4.26 in its entirety to only Commission regulation § 4.26(d), such that compliance with Commission regulation § 4.26(a) through (c), provisions that generally govern the use and amendment of this information, would be required, but filing with NFA prior to first use would not.

Consistent with the proposed amendments regarding QEP Disclosures for § 4.7 pools, the Commission also proposed disclosure requirements for § 4.7 trading programs under Commission regulation § 4.7(c)(1). Specifically, the Commission proposed to amend Commission regulation § 4.7(c)(1) to require CTAs to deliver certain disclosures to their § 4.7 advisory clients. The proposed disclosure requirements included a description of: (i) the trading program; (ii) certain persons to be identified; (iii) principal risk factors for the CTA's trading program; (iv) fees; (v) conflicts of interest; and (vi) targeted past performance information. Similar to the proposed amendments to Commission regulation § 4.7(b)(2)(i), the Commission proposed to establish these minimum disclosure requirements by rescinding or narrowing existing exemptions in Commission regulation § 4.7(c)(1) from Commission regulation §§ 4.31, 4.34, and 4.35.³² Proposed Commission regulation § 4.7(c)(2)(i)(G) continued to require that QEP Disclosures provide all additional disclosures necessary to make the information contained therein, in the context in which it is furnished, not misleading, and Proposed Commission regulation § 4.7(c)(2)(i)(H) continued to require a form statement

like that currently required by Commission regulation § 4.7(c)(1)(i).

Further, the Commission proposed to update corresponding recordkeeping, and use and amendment requirements for CTAs offering § 4.7 trading programs. Specifically, the Commission proposed to amend Commission regulation § 4.7(c)(2) to require CTAs to maintain QEP Disclosures among the other books and records for their § 4.7 trading programs, and make them available to the Commission, NFA, and the U.S. Department of Justice, in accordance with Commission regulation § 1.31. Additionally, the Commission proposed to narrow the exemption from Commission regulation § 4.36 in its entirety to only Commission regulation § 4.36(d), such that compliance with Commission regulation § 4.36(a) through (c), provisions that generally govern the use and amendment of this information, would be required, but filing with NFA prior to first use would not.

In the Proposal, the Commission explained that “[t]he definition of QEP in Regulation 4.7 encompasses a broad spectrum of market participants from large fund complexes and other institutional investors with significant assets under management to individuals with varying backgrounds and experience, each of which has vastly different resources available to insist upon the disclosure of information regarding the offered 4.7 pool or trading program and then to analyze whatever information is provided.”³³ Moreover, the Commission stated its concern that “individual natural persons, who meet the QEP definition through the Portfolio Requirement, but nonetheless do not command the assets of large financial institutions, likely lack the ability to demand the same level of transparency afforded through the prospect of additional significant asset allocations,” which, the Commission preliminarily expected, would result in their being more likely to rely upon whatever information the CPO or CTA chose to provide.³⁴ The Commission stated its preliminary belief that, “[t]his perceived disparity may increase the likelihood of CPOs and CTAs with less rigorous risk management and controls to seek capital from such individuals who are generally less able to engage in the same rigorous monitoring,”³⁵ as institutional

investors. As further support for the imposition of minimum disclosure requirements, the Commission also noted the “rapid and unrelenting pace”³⁶ of product innovation, for example in the digital asset space, increasing the possibility that “certain QEP participants and clients may not have the level of information necessary to fully appreciate the nature of the risk associated with their trading.”³⁷ The Commission preliminarily concluded in the Proposal, based upon its analysis of the regulatory history behind this regulation, the prevalence of § 4.7 offerings, and the myriad market and product developments since 1992, that “requiring the provision of specific minimum disclosures for CPOs and CTAs operating 4.7 pools and trading programs will assist in mitigating the customer protection gaps that have developed since 1992 by ensuring that QEPs receive the information necessary to make informed investment decisions, and that such disclosures are subject to Commission and NFA oversight.”³⁸ Further, in explaining the benefits of the proposed QEP Disclosure amendments, the Commission stated its belief that, these proposed amendments would mandate a minimum amount of transparency into § 4.7 pools and trading programs, which could help such QEPs protect themselves against excessive fees and self-dealing, and generally help insure that the products offered by such CPOs and CTAs are performing and being operated, as anticipated.³⁹ Additionally, the Commission explained its expectation that “mandating QEP Disclosures and requiring that they be materially accurate and complete, rather than just optional and not materially misleading, [would] benefit market participants and the public by ensuring that prospective investors would receive QEP Disclosures containing, at a minimum, certain important general and performance information that they can reliably assume is kept current and materially complete with respect to the items proposed to be required . . . [and that the proposed amendments] would allow for improved oversight of the regulated activities of CPOs and CTAs” by the Commission.⁴⁰ For these reasons, among others articulated in the Proposal, the Commission proposed specific minimum disclosures to bridge the customer protection gap that has, in

³³ Proposal, 88 FR 70856.

³⁴ *Id.*

³⁵ *Id.* (citing Susan Taylor Martin, How Tampa's James Cordier went from high roller to YouTube apology after losing \$150 million, Tampa Bay Times, Feb. 11, 2019, available at <https://www.tampabay.com/business/how-tampas-james-cordier-went-from-high-roller-to-youtube-apology-after-losing-150-million-2019206/>).

³⁶ Proposal, 88 FR 70857.

³⁷ *Id.*

³⁸ *Id.* at 70857–58.

³⁹ Proposal, 88 FR 70872.

⁴⁰ *Id.*

³¹ 17 CFR 1.31.

³² Proposal, 88 FR 70861.

its view, developed since the adoption of Commission regulation § 4.7 in 1992.

2. Feedback From Commenters

Generally, commenters were opposed to the proposed QEP Disclosures for § 4.7 CPOs and CTAs, citing a number of concerns relating to cost, purpose, practicality in certain common structuring scenarios, and redundancy. All seven commenters provided feedback on the proposed minimum disclosure requirements, including several that offered alternative approaches to the proposed method of adding minimum QEP Disclosures to Commission regulation § 4.7 for the Commission to consider.

A majority of the commenters opposed or disagreed with the proposed minimum disclosure requirements because they believed the additional requirements were unnecessary.⁴¹ One commenter opposed the proposed QEP Disclosures generally because they believe “imposing mandatory minimum disclosures would be premature,” “would not provide any protections above and beyond current regulations,” “could lead to the presentation of potentially misleading investor disclosures,” and because “the costs to § 4.7 CPOs and CTAs would be unduly burdensome.”⁴² This commenter disagreed that QEPs currently lack sufficient information to make informed decisions and stated that raising the Portfolio Requirement may mitigate the concerns the Commission expressed in the Proposal.⁴³ The commenter asserted further that the current standard in Commission regulation § 4.7 that requires disclosures, if any are provided, to not be misleading is sufficient because disclosures provided in the § 4.7 pool context have become market practice and are made to satisfy the preferences and demands of sophisticated investors.⁴⁴ Other commenters echoed this sentiment, with one suggesting that “private fund managers commonly include a description of the fund’s investment objectives and strategy in marketing materials and offering documents,”⁴⁵ and another stating that it would “essentially render the entire § 4.7 regime, and the exemptions provided thereunder, moot.”⁴⁶ Another commenter described the minimum QEP disclosure requirements as

“unnecessary to achieve the Commission’s policy goals and . . . unduly costly and even counterproductive,”⁴⁷ and further stated that they are “not aware that prospective or current QEP investors or clients in pools and trading accounts operated by these members, virtually all of which are qualified purchasers not subject to the Portfolio Requirement, have requested or otherwise indicated a need for such additional disclosure.”⁴⁸ Finally, NFA cautioned against the proposed disclosure requirements, and stated that “over the years NFA has received few complaints from § 4.7 exempt pool participants and managed account program clients that CPOs and CTAs have not provided them with information upon request.”⁴⁹ Several of these commenters specifically recommended that the Commission adopt the proposed amendments to the Portfolio Requirement, and then evaluate the § 4.7 population to determine whether the separately proposed minimum disclosure requirements are necessary.⁵⁰

Among the general opposition to the minimum disclosure requirements, multiple commenters disputed the Commission’s stated concern that some QEPs may lack the ability to demand the same level of transparency as those QEPs with significantly higher asset allocations, resulting in their being more likely to rely upon whatever information the CPO or CTA chose to provide. One commenter acknowledged that there could be a disparity in QEPs’ ability to obtain information, by suggesting that the minimum disclosure requirements should be limited to natural person QEPs, and stating that, “if the CFTC’s policy behind the Proposal is to ensure that investors who do not have leverage are provided minimum disclosures, then the focus

should be on investors who have direct privity with the CTA and do not have a large enough investment mandate to be able to negotiate disclosure.”⁵¹ A second commenter pointed to language within current Commission regulation § 4.7, in which “[p]rospective QEP clients of CTAs already have the right, under existing regulations, to decline to have their accounts treated as exempt accounts under Regulation 4.7.”⁵² Other commenters challenged the Commission’s concerns more generally.⁵³

Aside from this general opposition, some commenters provided specific feedback on the potential negative impacts the proposed minimum disclosure requirements may have on dually-registered investment advisers and complex fund structures that rely on § 4.7 exemptions.⁵⁴ One commenter stated that, “the proposed disclosure requirements create conflicts and duplicative burdens for CPOs and CTAs dually-registered as investment advisers with the SEC [Securities and Exchange Commission] when operating exempt pools or advising exempt accounts.”⁵⁵ Another commenter provided background, from the perspective of CTAs, on the “critical” regulatory relief provided by Commission regulation § 4.7 for registered and offshore funds requiring a registered CTA, explaining that CTAs registered as investment advisers are already subject to “extensive disclosure on Form ADV,” and that “both registered and offshore funds are currently required to provide robust disclosure documents that describe the fund’s investment objective, policies, and risks, and such disclosures necessarily describe the CTA’s trading strategy and associated

⁵¹ ICI Letter, at 9.

⁵² IAA Letter, at 5.

⁵³ See MFA Letter, at 6 (“There is no evidence cited in the [NPRM] or elsewhere, however, that QEPs currently lack sufficient information to make informed decisions.”); AIMA Letter, at 7 (“Second, the Commission concludes that the current exemption framework is insufficient because [it] fails to ensure that all QEPs (natural persons, specifically) can demand and receive the information necessary to make informed investment decisions and/or effectively monitor their investments. The Proposal, however, lacks a concrete example of any instance where this may be the case.”).

⁵⁴ MFA Letter, at 8; Dechert Letter, at 10; IAA Letter at 5; ICI Letter, at 3–7.

⁵⁵ Dechert Letter, at 10 (stating further that “CTAs that are SEC-registered investment advisers, like CPOs that are SEC-registered investment advisers, already distribute regulatory disclosures to investors, such as Form ADV, making it unnecessary for these CTAs to create new disclosure documents”). This commenter further asserted that the Commission’s concerns with respect “to natural person QEPs should also be sufficiently addressed by adjusting [the Portfolio Requirement].” *Id.*

⁴¹ See generally MFA Letter, at 6; SIFMA AMG Letter at 4; AIMA Letter at 2; IAA Comment Letter at 5.

⁴² MFA Letter, at 2.

⁴³ MFA Letter, at 6.

⁴⁴ MFA Letter, at 11.

⁴⁵ SIFMA AMG Letter, at 5.

⁴⁶ AIMA Letter, at 2.

⁴⁷ IAA Letter, at 5.

⁴⁸ *Id.*

⁴⁹ NFA Letter, at 3.

⁵⁰ See Dechert Letter, at 14 (“If the alternative approaches we articulate in this comment letter in response to the Proposal do not persuade the Commission, we would strongly counsel the Commission to limit the first stage of rulemaking in this area to the amendment of CFTC Rule 4.7 to increase the Portfolio Requirement to reflect inflation, as proposed, and then to study the effect that this change has on the types of QEPs the Commission seems most concerned about protecting.”); see also AIMA Letter, at 4–5 (“If the Portfolio Requirement thresholds are adjusted appropriately, then there is no reason why the Commission should also eliminate the disclosure exemptions under Regulation 4.7. The Commission should first evaluate whether the changes to the Portfolio Requirement thresholds address and/or mitigate the Commission’s perceived concerns about unequal bargaining or negotiating power among those QEPs that satisfy the new, higher standard.”).

risks.”⁵⁶ Multiple commenters also argued that the minimum disclosure requirements are either unnecessary or inappropriate when applied to common usage scenarios involving complex fund structures or scenarios in which the CPO or CTA relies upon Commission regulation § 4.7 solely because no other appropriate exemption for their activity exists.⁵⁷ One commenter argued that “layering” the current performance and disclosure rules on complex multi-strategy mandates “would not provide clearer or more accurate disclosures to investors,” and instead, “would potentially require any disclosures to attempt to compensate for the flexibility inherent in these products and potentially result in disclosures that are so generic as to be meaningless to investors.”⁵⁸ Another commenter stated that, “many of [their] CTA members are also CPOs and offer separate accounts only to QEPs who seek to invest a substantial amount of capital through a separate account structure rather than pool participation,” describing these account arrangements as “often heavily negotiated.”⁵⁹ Another commenter provided background on the relief Commission regulation § 4.7 provides to registered and offshore funds requiring a registered CTA, describing four common scenarios where investment advisers rely on Commission regulation § 4.7 for CTA compliance relief with respect to a registered or offshore fund requiring a registered CPO and CTA.⁶⁰ With respect to these CTA-specific scenarios, the commenter argued that if the proposed disclosure requirements were implemented in these contexts, commonly controlled entities would likely be required to provide disclosures to entities or persons that either already receive them, or already have access to such information, or would result in the Commission implementing regulatory authority over certain entities that the CFTC has traditionally sought not to oversee directly.⁶¹

Last, and perhaps most significantly, four commenters provided the

Commission with potential alternatives to the minimum disclosure requirement framework proposed in the NPRM. One commenter suggested that the Commission instead amend Commission regulation § 4.7 to require CPOs and CTAs to provide disclosures to QEP investors, the scope and substance of which, however, would be “determined at the discretion of the 4.7 CPO or CTA.”⁶² Another commenter suggested that the Commission instead consider limiting the required QEP Disclosures to “risk factors, the CTA’s trading programs, fees and conflicts of interest to be provided to clients who are (a) natural persons and (b) legal organizations who are not eligible contract participants.”⁶³ This commenter also requested that, “where such information is disclosed to clients or prospective clients through compliance with an existing regulatory regime (e.g., via disclosure in the CTA’s Form ADV Part 2 brochure), the Commission should permit satisfaction of the disclosure requirement by substituted compliance.”⁶⁴ A third commenter asked the Commission to consider adopting the disclosure requirements such that they would “not apply where exempt pool participants and exempt account clients qualify as QEPs under CFTC Rule 4.7(a)(2),” referring to those QEPs that are not subject to the Portfolio Requirement discussed in further detail below.⁶⁵ Finally, a fourth commenter opined that the minimum disclosure requirements “should only apply to Regulation 4.7 CTA clients that are natural persons who are residents of the United States.”⁶⁶

3. Further Consideration of Proposed Minimum QEP Disclosures

After considering the feedback received, the Commission has determined it appropriate to take additional time to consider the concerns articulated as well as the alternatives to the proposed QEP disclosure

amendments put forward by commenters. Therefore, the Final Rule does not adopt minimum disclosure requirements to Commission regulation § 4.7. Rather, the Commission is prioritizing in this Final Rule the adoption of amendments to Commission regulation § 4.7 that incorporate the proposed Portfolio Requirement increases in the QEP definition and add the monthly account statement schedule for certain § 4.7 pools, while it continues to evaluate regulatory alternatives and may adopt further changes in the future.

C. Updating Financial Thresholds in the Portfolio Requirement of the “Qualified Eligible Person” Definition

As explained briefly above, the Commission proposed to amend the definition of the “Portfolio Requirement,” in Commission regulation § 4.7 by updating its financial thresholds in a manner that accounts for the effects of inflation over the thirty-two years since their initial adoption with the intention of continuing to align the Portfolio Requirement with the Commission’s original regulatory intent.⁶⁷ Commission regulation § 4.7 bifurcates the definition of QEP into two different groups of persons that may qualify: (1) those persons⁶⁸ who do not need to satisfy an additional Portfolio Requirement to be considered a QEP; and (2) those persons who must satisfy the Portfolio Requirement to be considered a QEP.⁶⁹ The Commission further explained that the current Portfolio Requirement contains two thresholds whereby a person can be deemed a QEP: (1) owning securities (including pool participations) of issuers not affiliated with such person and other investments with an aggregate market value of at least \$2,000,000⁷⁰ (Securities Portfolio Test); or (2) having on deposit with a futures commission merchant (FCM), for its own account at any time during the six months preceding either the date of sale to that person of a pool participation in the § 4.7 pool or the date the person opens an account with the CTA for a § 4.7

⁵⁶ ICI Letter, at 8.

⁵⁷ SIFMA AMG Letter, at 5; IAA Letter, at 5, n.5; and, ICI Letter, at 4–7.

⁵⁸ MFA Letter, at 8.

⁵⁹ SIFMA AMG Letter, at 4 (arguing that “[t]hese investors have the power to request the information they require to make informed investment decisions and have little need for exhaustive mandated disclosures that were designed originally with retail clients in mind”).

⁶⁰ ICI Letter, at 4–7. These scenarios included: (1) CPOs and CTAs in a master-feeder relationship; (2) advisers and sub-advisers to a registered fund requiring CPO and CTA registration; (3) U.S. investment advisers to offshore funds; and (4) offshore advisers to offshore funds that also advise U.S. funds. *Id.*

⁶¹ See generally ICI Letter, at 4–7.

⁶² MFA Letter, at 12.

⁶³ SIFMA AMG Letter, at 5. The Commission notes that SIFMA AMG provided this specific recommendation only with respect to CTAs’ § 4.7 trading programs. SIFMA AMG did not provide a similar recommendation for CPOs and their § 4.7 pools.

⁶⁴ *Id.*

⁶⁵ Dechert Letter, at 5. This approach was also acknowledged by other commenters in both comment letters and during *ex parte* meetings with Commission staff as a possible, acceptable alternative to the Proposal. See, e.g., MFA Comment Letter II, at 2 (stating “if the CFTC decides to move forward with any proposed disclosure requirements, it is critical that the Commission exempt CPOs and CTAs with respect to 4.7(a)(2) investors from the disclosure requirements”).

⁶⁶ ICI Letter, at 9.

⁶⁷ Proposal, 88 FR 70853–55.

⁶⁸ See 17 CFR 1.3 (defining “person” as including individuals, associations, partnerships, corporations, and trusts).

⁶⁹ Proposal, 88 FR 70853, n. 17–18 (describing these two different types of QEPs in further detail).

⁷⁰ 17 CFR 4.7(a)(1)(v)(A), or as amended by the Final Rule, 17 CFR 4.7(a)(5)(i). The Commission explains further below that the Final Rule adopts several technical amendments reorganizing and renumbering portions of Commission regulation § 4.7, including the paragraph containing definitions. As a result of the Final Rule, the new citations for the Portfolio Requirement thresholds will be 17 CFR 4.7(a)(5)(i) through (iii).

trading program, at least \$200,000 in exchange-specified initial margin and option premiums, together with required minimum security deposits for retail forex transactions, for commodity interest transactions⁷¹ (Initial Margin and Premium Test). Commission regulation § 4.7 also provides that persons may satisfy the Portfolio Requirement by owning a portfolio comprised of a combination of the funds or property specified in the Securities Portfolio Test and the Initial Margin and Premium Test, which, when expressed as percentages of the required amounts, meet or exceed 100%.⁷² Therefore, if a person required to satisfy the Portfolio Requirement meets one of the tests (or some combination of the two), as described above, the CPO or CTA may consider such person qualified as a QEP and accept them as a § 4.7 pool participant or advisory client, respectively.

In the Proposal, the Commission explained its preliminary conclusions that updating the dollar thresholds within the Securities Portfolio Test and the Initial Margin and Premium Test would be appropriate because the thresholds had not been updated since their adoption in 1992.⁷³ The Commission further explained its belief that the Consumer Price Index for All Urban Consumers (CPI-U) and the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W) would be suitable benchmarks for determining the general impact of inflationary pressures on the existing Portfolio Requirement thresholds; employing those indexes, the Commission ultimately proposed doubling the Securities Portfolio Test to \$4,000,000, and the Initial Margin and Premium Test to \$400,000, while also retaining the existing option to meet the Portfolio Requirement through a combination of the two tests adding up to 100%.⁷⁴ Although the Commission acknowledged that the proposed update to the dollar thresholds were not an exact reflection of the impact of inflation,⁷⁵ the Commission reasoned that approximating these thresholds to the nearest million and hundred thousand provided clear and fair thresholds that would better facilitate

compliance.⁷⁶ After careful consideration of the comments received, as well as additional analysis of the benchmarks the Commission initially used to determine the impact of inflation on the existing Portfolio Requirement thresholds, the Commission is adopting the amendments to the Portfolio Requirement as proposed.

Commenters generally supported the Commission's proposed amendments to the Portfolio Requirement. Of the eight responses the Commission received on the Proposal as a whole, five commenters responded directly to the Commission's proposal to update the Portfolio Requirement.⁷⁷ MFA, SIFMA AMG, AIMA, IAA, and Dechert supported the Commission's proposal to update the Portfolio Requirement,⁷⁸ although some commenters further stated that the adoption of these threshold increases should not be coupled with the addition of minimum disclosure requirements in Commission regulation § 4.7. In particular, several commenters expressed their view that appropriately updating the Portfolio Requirement thresholds should alleviate the concerns raised by the Commission in the NPRM by providing additional customer protection for natural persons (and other QEPs subject to the Portfolio Requirement) and modernizing Commission regulation § 4.7, which would thereby render any additional disclosure requirements unnecessary.⁷⁹

⁷⁶ *Id.*

⁷⁷ See SIFMA AMG Letter, at 11; AIMA Letter, at 4; IAA Letter, at 2; Dechert Letter, at 14.

⁷⁸ See MFA Letter, at 3 (explaining that "an increase in the investor qualification thresholds for QEPs could modernize CFTC Regulation 4.7 to meet contemporary expectations regarding sophisticated investors," and that the proposed increases "would bring the Portfolio Requirement monetary threshold into closer alignment with the qualified purchaser . . . standard, consistent with the investor base for many 4.7 pools"); SIFMA AMG Letter, at 11 ("[W]e think it makes sense to update the Portfolio Requirement to ensure that QEPs remain limited to those investors who are truly sophisticated."); AIMA Letter, at 4 ("We broadly support the proposed changes to the Portfolio Requirement Thresholds."); IAA Letter, at 2 ("We do not object to the Commission's proposal to update the Portfolio Requirement thresholds for QEPs to adjust for inflation."); Dechert Letter, at 14 ("[W]e do not have an issue with CFTC's proposal to increase the two thresholds in the Portfolio Requirement.").

⁷⁹ See, e.g., MFA Letter, at 5 ("Doubling the QEP dollar thresholds is sufficient to address the Commission's current investor protection and modernization goals, without conditioning the increase on the adoption of a prescriptive, retail oriented disclosure regime contained in the Disclosure and Performance Rules."); SIFMA AMG Letter, at 11 ("In our view, this update should address the Commission's concerns articulated in the Proposal at large regarding investor sophistication and access to information, thus obviating the need to impose mandatory disclosure requirements in addition."); AIMA Letter, at 4 ("If

The Commission agrees that increasing the thresholds brings Commission regulation § 4.7 back into alignment with the Commission's original intention in 1992 for the purpose of differentiating between retail investors and more sophisticated market participants. The increases to the Portfolio Requirement thresholds ensure that persons unable to meet those metrics receive the full panoply of disclosures and other customer protections required for non-QEP pool participants and advisory clients.

Although the Commission is not finalizing the proposed amendments that would add minimum disclosure requirements to Commission regulation § 4.7 in this Final Rule, the Commission notes that commenters asserted that raising the Portfolio Requirement thresholds would also address the Commission's concerns regarding the informational discrepancy between CPOs' and CTAs' prospective and actual pool participants and advisory clients. The Commission proposed the increases to the thresholds in the Portfolio Requirement to ensure that it continued to serve as "objective criteria" to distinguish between retail participants in the commodity interest markets and those persons "with a high degree of sophistication with regard to investments as well as financial resources to withstand the risk of their investments."⁸⁰ Essentially, increasing the Portfolio Requirement thresholds in the manner proposed in the NPRM effectively bridges the financial gap that has developed between the amounts the Commission adopted in 1992 and the actual buying power of those amounts in 2024, due to inflationary effects experienced in that time period.

In addition to general support from commenters, the Commission believes that updated information from the indexes used to benchmark the proposed thresholds within the Portfolio Requirement continues to support the proposed increases. In developing this Final Rule, the Commission revisited the two inflation indexes published by the United States Bureau of Labor Statistics (BLS) used to devise the proposed amendments to the Portfolio Requirement. As explained in the Proposal, the Commission consulted

the Portfolio Requirement thresholds are adjusted appropriately, then there is no reason why the Commission should also eliminate the disclosure exemptions under Regulation 4.7."); IAA Letter, at 2 ("We believe that raising [the Portfolio Requirement thresholds] should be sufficient to address the Commission's concerns, and that the additional proposed disclosures are not necessary.").

⁸⁰ Proposal, 88 FR 70854 (citing the 1992 Proposed Rule, 57 FR 3152).

⁷¹ 17 CFR 4.7(a)(1)(v)(B), or as amended by the Final Rule, 17 CFR 4.7(a)(5)(ii).

⁷² 17 CFR 4.7(a)(1)(v)(C), or as amended by the Final Rule, 17 CFR 4.7(a)(5)(iii).

⁷³ Proposal, 88 FR 70854.

⁷⁴ *Id.*

⁷⁵ Using the indexes, as of February 2023, the Commission explained in the NPRM that \$2,000,000 had the same buying power as \$4,270,000, and \$200,000 had the same buying power as approximately \$427,000. *Id.*

the CPI-U and CPI-W to understand the approximate effect of inflation on the dollar value thresholds within the Portfolio Requirement and the current buying power of those thresholds.⁸¹ The purpose of consulting these benchmarks was to determine whether the dollar thresholds within the Portfolio Requirement still reflect the heightened standard of investor activity and sophistication that the Commission considered sufficient for certain persons to qualify as a QEP in adopting the Portfolio Requirement in 1992. At the time of the Proposal, the Commission preliminarily concluded that the thresholds within the Portfolio Requirement were significantly devalued by over three decades of inflationary effects, such that the thresholds no longer served as the investor protection guardrails that the Commission originally intended.⁸² If left unaddressed, the Commission believes that the gap between the actual buying power of the original Portfolio Requirement thresholds and the Commission's original intent of limiting QEPs to financially sophisticated persons with significant commodity interest trading experience will only widen. In the Proposal, the Commission specifically requested feedback from commenters on whether the CPI-U and CPI-W indexes were "the most appropriate for considering inflation on the thresholds within the Portfolio

Requirement," and if not, the Commission also requested feedback on any other indexes or methods it should use in assessing the effect of inflation.⁸³ The Commission did not receive any feedback in response to this question, and therefore, will continue to use the CPI-U and CPI-W indexes as benchmarks for its analysis. Using the same example, the Commission used in the Proposal, based on analysis using CPI-U data, as of July 2024, the \$2,000,000 threshold in the Securities Portfolio Test has the same buying power as approximately \$4,464,726, and the \$200,000 threshold in the Initial Margin and Premiums Test has the same buying power as approximately \$446,472.⁸⁴ As shown by the example, the disparity in buying power will continue to be exacerbated over time.

Although the Commission believes the updated information from the inflation indexes justifies updating the Portfolio Requirement thresholds, some commenters raised concerns that an increased Portfolio Requirement would have wider consequences. One commenter raised a concern that, if the Commission significantly raised the Portfolio Requirement's financial standards, it "may move certain persons that may desire to participate in a 4.7 pool or managed account program further away from the SEC's current accredited investor qualification standards for private offerings," and recommended that the Commission work with the SEC to review the accredited investor definition and determine if any changes are appropriate, rather than update the Portfolio Requirement thresholds on its own.⁸⁵ The Commission agrees with the commenter that it is desirable to harmonize overlapping regulatory

regimes where possible and appropriate, and recognizes that it is perhaps particularly relevant to Commission regulation § 4.7, where the Commission specifically identified and utilized the SEC's accredited investor definition as a "foundation" for developing the exemption.⁸⁶ Despite that acknowledgement, the Commission is not persuaded that increasing the financial thresholds within the Portfolio Requirement would create a large enough gap between the two frameworks, so as to render them unworkable in tandem. The Portfolio Requirement is a unique feature of Commission regulation § 4.7 that has never appeared as a qualification in the SEC's accredited investor definition. In 1992, as part of the Commission's discussion of the SEC's accredited investor definition serving as a "foundation" for Commission regulation § 4.7, the Commission stated that it "[proposed] a definition of QEP that is designed generally to include persons who qualify as accredited investors under Regulation D [17 CFR 230.500 through 230.508] and who meet certain additional qualifications."⁸⁷ The Commission was clear in 1992 that the Portfolio Requirement was intended to be an "additional qualification" on top of meeting the accredited investor definition, and that its consideration of aspects of the accredited investor definition in developing Commission regulation § 4.7 were with respect to the categories of QEPs and not the Portfolio Requirement. The Portfolio Requirement is a CFTC-only component of Commission regulation § 4.7 that was developed intentionally to impose a heightened standard for QEPs as opposed to simply relying on the provisions of the securities laws. It is entirely plausible that, under the existing frameworks, a person may qualify as an accredited investor, but also not be a QEP. For example, § 230.501(a)(6) of Regulation D defines an accredited investor as any natural person who had an individual income in excess of \$200,000 in each of the two most recent years, or joint income with that person's spouse in excess of \$300,000 in each of those years.⁸⁸ If a natural person narrowly meets that accredited investor income test, it is entirely possible that they do not have sufficient assets to meet the Securities Portfolio Test, or sufficient commodity interest trading to meet the Initial Margin and Premiums Test under the current Portfolio Requirement in

⁸¹ See the U.S. BLS Handbook of Methods, for more information on the CPI, CPI-U, and CPI-W, available at <https://www.bls.gov/opub/hom/cpi/presentation.htm>. As described by the BLS Handbook of Methods, CPI-U represents the buying habits of the residents of urban and metropolitan areas in the United States and covers over 90 percent of the U.S. population. *Id.* Comparatively, the CPI-W is computed using the same prices as the CPI-U, but the weights of the CPI-W are based on a subset of the CPI-U population, covering approximately 30 percent of the U.S. population. *Id.* The CPI-W also includes households where more than one-half of the household's earners must have been employed for at least 37 weeks during the previous 12 months. *Id.* Given the relevance of these indexes to the population of natural persons that may qualify as QEPs via the Portfolio Requirement, the Commission believes these indexes are the most appropriate to use in determining today's buying power of the Portfolio Requirement's monetary thresholds established in 1992.

⁸² See Proposal, 88 FR 70854. The indexes show that inflation has had an appreciable effect on the monetary thresholds promulgated in the 1992 Final Rule. The CPI-U and CPI-W data expose that the current thresholds may no longer be indicative of a high level of investor sophistication, acumen, and resources that the Commission anticipated when the Portfolio Requirement was promulgated. Based on analysis using CPI-U data, for example, as of February 2023, the Securities Portfolio Test's \$2,000,000 threshold has equal purchasing power as approximately \$4,270,000, and the \$200,000 specification in the Initial Margin and Premiums Test has equal purchasing power as approximately \$427,000. See also *id.* at 70854, n. 30.

⁸³ *Id.* at 70855.

⁸⁴ The actual calculator for CPI-U can be found at https://www.bls.gov/data/inflation_calculator.htm. Similar to the Proposal, the Commission is choosing to include the July 2024 CPI-U data above because it provides a clear example of today's buying power of the Portfolio Requirement, as it was established in August 1992, and because the data can be easily accessed and verified via the BLS inflation calculator link provided herein. In comparing the results of each index, as applied to the Portfolio Requirement thresholds, the Commission found no material difference between the CPI-W and CPI-U. Analysis using the CPI-W provided similar buying power figures to those produced by the CPI-U analysis. Given that the Commission is proposing updated thresholds rounded down to the nearest million and hundred thousand, the Commission believes that providing the CPI-U analysis is sufficient for purposes of this Final Rule.

⁸⁵ NFA Letter, at 3. NFA also stated that the Commission, in its 1992 Proposal, acknowledged that the SEC's accredited investor definition under SEC Regulation D was used as the "foundation" to define categories of QEPs. See also 57 FR 3148, 3151–3152 (Jan. 28, 1992) (1992 Proposal).

⁸⁶ 1992 Proposal, 57 FR 3151.

⁸⁷ *Id.* (emphasis added).

⁸⁸ 17 CFR 230.501(a)(6).

Commission regulation § 4.7. To put it simply, in the context of natural persons, the accredited investor definition attempts to measure financial sophistication by annual income or net worth, whereas the Portfolio Requirement is focused on a person's experience trading and managing a portfolio of sufficient size to demonstrate an understanding of the risks in the securities and commodity interest markets; the latter being arguably more relevant to assessing a person's sophistication and investment acumen given the complexity and unique risks associated with the commodity interest markets.⁸⁹

Moreover, not all persons are required to meet the Portfolio Requirement to be QEPs. The Portfolio Requirement only applies to persons listed under current Commission regulation § 4.7(a)(3),⁹⁰ whereas those categories of persons listed under current Commission regulation § 4.7(a)(2) do not have to meet its terms to be QEPs.⁹¹ In creating

⁸⁹ See 1992 Final Rule, 57 FR 34854, quoting 1992 Proposal, 57 FR 3151 (explaining that the Commission intended to define QEP status by means of objective criteria that such persons possess either the investment expertise and experience necessary to understand the risks involved, as evidenced by the registered status of certain investment professionals, or have an investment portfolio of sufficient size to indicate that the participant has substantial investment experience and thus a high degree of sophistication with regard to investments as well as financial resources to withstand the risk of their investments).

⁹⁰ This list includes, but is not limited to: (1) certain investment companies registered under the Investment Company Act of 1940 (ICA) or business development companies as defined in section 2(a)(48) of the ICA; (2) banks as defined in section 3(a)(2) of the Securities Act of 1933 (Securities Act); or any savings and loan association or other institution defined in section 3(a)(5)(A) of the Securities Act acting for its own account or for the account of a QEP; (3) certain insurance companies acting for their own account or that of a QEP; (4) certain state employee benefit plans; (5) certain employee benefit plans within the meaning of the Employee Retirement Income Security Act of 1974 (ERISA); (6) private business development companies; (7) certain organizations described in section 501(c)(3) of the Internal Revenue Code (IRC) with total assets in excess of \$5,000,000; (8) certain corporations, Massachusetts or similar business trusts, or partnerships, limited liability companies or similar business ventures; (9) natural persons meeting the individual net worth or joint net worth tests within the "accredited investor" definition; (10) natural persons who would otherwise be considered accredited investors; (11) certain pools, trusts, insurance company separate accounts, or bank collective trusts; and (12) certain government entities.

⁹¹ This list includes, but is not limited to: (1) registered FCMs, registered retail foreign exchange dealers (RFEDs), registered swap dealers, and principals thereof; (2) a registered broker or dealer, or principal thereof; (3) certain registered CPOs, and principals thereof (active for two or more years, and \$5,000,000 in total aggregate commodity pool assets); (4) certain registered CTAs, and principals thereof (active for two or more years, and advising commodity accounts, in the aggregate, of \$5,000,000

and adopting the QEP definition and Commission regulation § 4.7, the Commission viewed these two categories as separate "classes" and intentionally provided an additional eligibility condition, in the form of the Portfolio Requirement, for those persons listed in current Commission regulation § 4.7(a)(3).⁹² The amendments to the financial thresholds being adopted today do not expand the Portfolio Requirement to the other persons enumerated under current Commission regulation § 4.7(a)(2) or otherwise alter these two original categories of QEPs. The establishment of the Portfolio Requirement was an intentional, alternative mechanism for qualification as a QEP, functioning independent of the SEC's accredited investor definition, and has been part of the terms of Commission regulation § 4.7 since its inception in 1992. As such, the Commission is not persuaded that updating the Portfolio Requirement by adjusting its thresholds would meaningfully disrupt existing harmonization between CFTC and SEC regulatory regimes, as the two standards were never identical and were not intended to be. Nor does the Commission believe that it should delay increasing the Portfolio Requirement until the accredited investor definition is otherwise amended.

Another commenter expressed concern that the increases to the financial thresholds within the Portfolio Requirement could have negative effects on persons who currently qualify as QEPs, but would no longer be considered QEPs under the updated Portfolio Requirement.⁹³ Specifically, the commenter advocated for the grandfathering of investors who are currently QEPs, but would no longer qualify as such under the increased Portfolio Requirement, and encouraged the Commission to "clarify and explain its expectations with respect to 4.7 offerings with pool participants that are both QEPs, and former QEPs that no longer satisfy the [increased] Portfolio Requirement."⁹⁴ In the Proposal, the Commission specifically requested any

or more); (5) certain investment advisers registered under the Investment Advisers Act of 1940 (IAA), and principals thereof; (6) "qualified purchasers" as defined in section 2(a)(51)(A) of the ICA; (7) "knowledgeable employees" as defined in 17 CFR 270.3c-5 pursuant to the ICA; (8) certain persons associated with an exempt pool or account; (9) certain trusts; (10) organizations described in section 501(c)(3) of the IRC, where the trustee, founder, or person making investment decisions is also a QEP; (11) non-United States persons; and (12) exempt pools.

⁹² 1992 Proposal, 57 FR 3152.

⁹³ MFA Letter, at 4.

⁹⁴ *Id.*

data or information from CPOs or CTAs that utilize Commission regulation § 4.7 on the number of advisory clients and pool participants that would be directly affected by the increase.⁹⁵ Despite raising this concern and the Commission's specific request, neither this commenter nor any other provided information or data on the number of advisory clients or pool participants that currently qualify as QEPs via the existing Portfolio Requirement, but would not so qualify if the increased thresholds are adopted.

Notwithstanding the lack of specific information to assess the magnitude of the class of persons affected, the Commission acknowledges that some persons will fall within this "gap" population that would no longer be considered QEPs under the updated Portfolio Requirement.⁹⁶ Because of that reality, the Commission preliminarily addressed its position with respect to such former QEPs within the Proposal.⁹⁷ For the sake of clarity, however, the Commission today restates its position below on how it expects CPOs and CTAs to comply with the updated Portfolio Requirement for its advisory clients or pool participants that previously qualified as QEPs, but would not so qualify under the updated Portfolio Requirement.

The Commission intends to retain, and will apply, the provision which requires that, for persons that must

⁹⁵ See Proposal, 88 FR 70855, Request #2 ("The Commission is also seeking any data or information, from CPOs and CTAs that utilize Regulation 4.7, on the estimated number of advisory clients and pool participants that currently qualify as QEPs via the existing Portfolio Requirement, but would not so qualify if the increased monetary thresholds in the Portfolio Requirement described above are adopted.").

⁹⁶ The only mechanism available for the Commission to confirm the existence of this population would be to review all documents required to be kept by § 4.7 CPOs and CTAs that validate their advisory clients' or pool participants' status as QEPs and assess how many would fall within the "gap" population.

⁹⁷ Proposal, 88 FR 70854–55 ("Acknowledging that the Portfolio Requirement will likely result in a certain portion of currently-qualifying QEPs no longer meeting the thresholds, the Commission noted that current Regulation 4.7(a)(3) provides that CPOs must assess a person's QEP status at the time of sale of any pool participation units including satisfying the Portfolio Requirement. Likewise, CTAs must make a similar assessment at the time that a person opens an exempt account. As opposed to requiring mandatory redemptions or terminations of advisory relationships for those current QEPs who may not meet the proposed heightened thresholds, the Commission expects that continuing this requirement minimizes the potential for disruption to the 4.7 pool or trading program, as well as possible negative consequences for the current QEPs. Therefore, the proposal was for the retaining the requirements of Regulation 4.7(a)(3) in Proposed Regulation 4.7(a)(6)(ii). Additionally the Commission sought comment on this issue in the proposal.).

satisfy the Portfolio Requirement, a CPO or CTA must have the reasonable belief, at the time of sale of a pool participation in an exempt pool, or at the time that a person opens an exempt account, that such person satisfies the Portfolio Requirement. In effect, if a CPO or CTA has previously sold a pool participation or opened an exempt account for a person that qualified as a QEP under the previous Portfolio Requirement, but who does not meet the updated Portfolio Requirement, the CPO or CTA would not be required to redeem such person's pool participations, or to terminate the advisory relationship with that person. However, a CPO or CTA would not be permitted to sell any additional pool participations or open any additional exempt accounts for any person that does not meet the updated Portfolio Requirement. The avoidance of required redemption or account closure should limit any potential disruptions or negative consequences either to the § 4.7 pool or trading program, or the pool participant or advisory client.

The Commission believes, however, that it would run counter to the intent of the updated Portfolio Requirement to permit a wholesale grandfathering of any persons who had previously been considered QEPs prior to the update. Additionally, the Commission is concerned that doing so may lead to an influx of persons into § 4.7 pools and trading programs prior to the implementation date of the updated Portfolio Requirement, solely to evade the increased financial thresholds. The Commission notes that, pursuant to current Commission regulation § 4.7 requirements, CPOs and CTAs are responsible for determining the QEP status of their prospective pool participants or advisory clients, regardless of how such QEP meets that definition, and must retain evidence of such determinations as part of their books and records.⁹⁸

D. Permitting Monthly Account Statements for Certain § 4.7 Pools Consistent With Commission Exemptive Letters

As the Commission explained in the Proposal, Commission regulation § 4.7(b)(3) provides an exemption from the requirement in Commission regulation § 4.22(a) and (b) that CPOs provide monthly account statements containing specific information to participants in their commodity pools.⁹⁹

With respect to § 4.7 pools, CPOs are permitted to distribute account statements no less frequently than quarterly within 30 days after the end of the reporting period.¹⁰⁰ The Commission noted, however, that CPOs of § 4.7 pools that are “Funds of Funds”¹⁰¹ have reported to Commission staff that they often have difficulty complying with the quarterly account statement schedule required by Commission regulation § 4.7(b)(3). The Commission stated further that such CPOs regularly request exemptive letters from the Commission to permit them to follow an alternate account statement schedule, explaining that because they cannot control the timing of when they receive financial information from underlying investee collective investment vehicles, investor Fund of Funds CPOs often do not receive the requisite information for their own § 4.7 pool periodic reporting until the 30-day period for distribution is nearly expired. The Commission explained that, over the years, it has routinely granted these exemptive letter requests, permitting requesting CPOs to distribute monthly, rather than quarterly, account statements for their § 4.7 Fund of Funds pools within 45 days of the month-end,¹⁰² and that this approach allowed the requesting CPOs additional time to receive and gather the information required for their account statements, while also ensuring that QEP pool participants receive both more accurate and more frequent reporting.

Consistent with its past efforts to memorialize routinely granted Commission letter relief via regulatory amendments, the Commission proposed to add paragraph (b)(3)(iv) to Commission regulation § 4.7, noting that the amendment was intended to streamline availability, provide consistency, and eliminate the need for Commission staff to process and respond to requests individually.¹⁰³ Proposed Commission regulation § 4.7(b)(3)(iv) stated, where the exempt pool is invested in one or more other pools or funds operated by third parties, the commodity pool operator may choose instead to prepare and distribute to its pool participants statements on a monthly basis within 45 days of the month-end, provided that such account statements otherwise meet the requirements of Commission regulation

§ 4.7(b)(3), and that the CPO notifies its § 4.7 pool participants of this alternate distribution schedule either in the pool's offering memorandum, or upon adoption of this reporting schedule.¹⁰⁴ The Commission requested comment on the proposed amendment, in particular whether it effectively creates a mechanism in Regulation § 4.7(b)(3) that is equivalent to the exemptive letters currently issued by the Commission, and whether the alternate account statement distribution schedule and notice requirements are clear.¹⁰⁵

In response to this aspect of the NPRM, the Commission received positive feedback from multiple commenters, with one commenter noting specifically that “seeking and receiving the exemptive relief has come with a time and cost burden for CPOs” operating § 4.7 Fund of Funds pools and indicating that the proposed amendment would be a welcome alternative to that process.¹⁰⁶ Given the positive public comments, the lack of any suggested changes to this amendment, as well as its continued belief that considering and adopting regulatory amendments consistent with staff letter relief provides clarity, consistency, and streamlines availability, the Commission is adopting Proposed Commission regulation § 4.7(b)(3)(iv) as proposed.

E. Other Technical Amendments

The Proposal also included a number of technical amendments to Commission regulation § 4.7 designed to improve its efficiency and usefulness for intermediaries and their prospective and actual QEP pool participants and advisory clients, as well as the general public.¹⁰⁷ For example, the Commission proposed to delete the introductory paragraph to Commission regulation § 4.7 and to generally restructure the definitions section in Commission regulation § 4.7(a), eliminating what it viewed as unnecessary subparagraph levels in the QEP definition and alphabetizing the definitions for ease of reference. The Commission also proposed additional amendments to ensure that cross-references within Commission regulation § 4.7 and in other part 4 regulations were accurate.

The Commission sought comment on those technical amendments and requested commenters detail any other technical amendments it should consider for ease of use, as well as

¹⁰⁰ 17 CFR 4.7(b)(3)(i).

¹⁰¹ In the Proposal, the Commission defined “Funds of Funds” as pools that invest in unrelated funds, pools, or other collective investment vehicles. Proposal, 88 FR 70856, n. 42.

¹⁰² Proposal, 88 FR 70863 (citing CFTC Letters 18–29, 19–01, 19–03, 20–11, 21–16, and 23–04).

¹⁰³ *Id.*

¹⁰⁴ Proposal, 88 FR 70878.

¹⁰⁵ *Id.* at 70863.

¹⁰⁶ SIFMA AMG Letter, at 11; IAA Letter, at 7; NFA Letter, at 5; Dechert Letter, at 11.

¹⁰⁷ Proposal, 88 FR 70863.

⁹⁸ See 17 CFR 4.7(b)(5) and (c)(2) (requiring CPOs and CTAs to maintain books and records including, without limitation, records relating to the qualifications of qualified eligible persons).

⁹⁹ Proposal, 88 FR 70863 (citing 17 CFR 4.7(b)(3), 4.22(a) and (b)).

whether there were any other cross-references within Commission regulation § 4.7 not addressed by the Proposal that should be corrected. The Commission received no comments on these technical amendments, and no commenters identified additional technical amendments or corrections that it should consider. Nevertheless, as a result of the reorganization of the definitions in Commission regulation § 4.7 accomplished by this Final Rule, the Commission has identified several regulations outside of 17 CFR part 4 that now require technical corrections because they refer to certain definitions in Commission regulation § 4.7. Specifically, the Commission is correcting references to defined terms in Commission regulation § 4.7 found in Commission regulation §§ 1.35, 3.10, 30.6, 43.6, and 75.10. Therefore, the Commission is adopting the technical amendments in the NPRM largely as proposed, along with technical corrections to the regulatory cross-references outside of part 4 that are listed herein.

F. Effective and Compliance Dates for the Final Rule

In the Proposal, the Commission requested feedback from commenters on the time needed to comply with the proposed Portfolio Requirement update and the proposed minimum disclosure requirements.¹⁰⁸ The Commission only received one comment in response, requesting an 18-month implementation timeline for the proposed minimum disclosure requirements.¹⁰⁹ As discussed above, the Final Rule is not adopting minimum disclosure requirements in Commission regulation § 4.7 at this time. Nonetheless, the Commission is adopting distinct compliance dates for each remaining component of the Final Rule.

The compliance date for the increased Portfolio Requirement thresholds shall be six months from publication of the Final Rule in the **Federal Register**. As discussed in section II.C above, the

updated Portfolio Requirement will require § 4.7 CPOs and CTAs to adjust their processes for assessing the QEP status for both new and existing pool participants and advisory clients. However, given that the Portfolio Requirement update would not require § 4.7 CPOs and CTAs to redeem pool participations or otherwise end advisory relationships with those QEPs who no longer meet the Portfolio Requirement, as amended by the Final Rule, and that § 4.7 CPOs and CTAs only need to update their QEP evaluation processes with the new thresholds on a forward-looking basis, the Commission believes a 6-month implementation period is appropriate.¹¹⁰

Finally, the component of the Final Rule permitting alternative monthly account statement schedule for certain § 4.7 pools that are Funds of Funds, *i.e.*, new Commission regulation § 4.7(b)(3)(iv), shall be effective as of the Final Rule's effective date, as described above, and following the effective date, compliance will be required when a CPO elects to utilize this schedule for a qualifying § 4.7 pool.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires that Federal agencies, in promulgating regulations, consider whether the regulations they propose will have a significant economic impact on a substantial number of small entities, and if so, to provide a regulatory flexibility analysis regarding the economic impact on those entities.¹¹¹ If the rules are determined to have a significant economic impact, such agencies must provide a regulatory flexibility analysis regarding such economic impact. Each Federal agency is required to conduct an initial and final regulatory flexibility analysis for each rule of general applicability for which the agency issues a general notice of proposed rulemaking. The Final Rule amendments adopted by the Commission today would affect only persons registered or required to be registered as CPOs and CTAs and those commodity pools and trading programs operated under Commission regulation § 4.7 and offered solely to QEPs.

1. CPOs

The Commission has previously established certain definitions of “small entities” to be used by the Commission

in evaluating the impact of its rules on such entities in accordance with the requirements of the RFA.¹¹² With respect to CPOs, the Commission previously has determined that a CPO is a small entity for purposes of the RFA, only if it meets the criteria for an exemption from registration under Commission regulation § 4.13(a)(2).¹¹³ The regulations adopted in this Final Rule apply to persons registered or required to be registered as CPOs with the Commission (specifically, those registered CPOs whose prospective and actual pool participants are restricted to QEPs) and/or provide relief to qualifying registrants from certain periodic reporting burdens. Accordingly, the Chairman, on behalf of the Commission, certifies pursuant to 5 U.S.C. 605(b) that this Final Rule will not have a significant economic impact on a substantial number of small entities, with respect to CPOs.

2. CTAs

Regarding CTAs, the Commission has previously considered whether such registrants would be deemed small entities for purposes of the RFA on a case-by-case basis, in the context of the particular Commission regulation at issue.¹¹⁴ Because certain of these registered CTAs may be small entities for the purposes of the RFA, the Commission considered in the NPRM whether the proposed amendments would have a significant economic impact on such registrants.¹¹⁵ The Commission received no comments on the initial regulatory flexibility analysis conducted in the Proposal.

The portions of the Final Rule directly impacting CTAs would affect only CTAs registered or required to register with the Commission that offer and operate trading programs designed for QEPs. Given that the Commission has determined to finalize only the Portfolio Requirement increases in this Final Rule, the Commission believes that the Final Rule amendments will have almost no economic impact on registered CTAs offering § 4.7 trading programs because, beyond increasing

¹⁰⁸ Proposal, 88 FR 70855 (“3. How much time would CPOs and CTAs need to determine that their existing QEP pool participants and clients would continue to satisfy the increased Securities Portfolio or Initial Margin and Premium Tests, if adopted as proposed?”); *see also* Proposal, 88 FR 70859 (“Should the Commission consider an implementation period for the proposed amendments, and if so, how much time should the Commission allow for CPOs and CTAs to develop and prepare QEP Disclosures that would comply with the proposed amendments?”).

¹⁰⁹ SIFMA Letter, at 11 (“If, however, the Commission declines to do so, we ask that the Commission allow for at least an 18-month compliance period to allow CPOs and CTAs adequate time to develop the necessary compliance programs.”).

¹¹⁰ *See* discussion in section II.C above for more detail on the implementation and applicability of the amended Portfolio Requirement to existing QEP pool participants and advisory clients.

¹¹¹ 5 U.S.C. 601, *et seq.*

¹¹² *See, e.g.*, Policy Statement and Establishment of Definitions of “Small Entities” for Purposes of the Regulatory Flexibility Act, 47 FR 18618, 18620 (Apr. 30, 1982).

¹¹³ *Id.* at 18619–20. Commission regulation § 4.13(a)(2) exempts a person from registration as a CPO when: (1) none of the pools operated by that person has more than 15 participants at any time, and (2) when excluding certain sources of funding, the total gross capital contributions the person receives for units of participation in all of the pools it operates or intends to operate do not, in the aggregate, exceed \$400,000. *See* 17 CFR 4.13(a)(2).

¹¹⁴ *Id.* at 18620.

¹¹⁵ Proposal, 88 FR 70863–66.

the thresholds in the Portfolio Requirement, the Final Rule does not add any other compliance burdens for CTAs.

As stated above, the amendments adopted today primarily impact registered CTAs offering § 4.7 trading programs to QEP advisory clients and claiming the compliance exemptions currently offered by Commission regulation § 4.7. As explained in the NPRM, data on the specific size of registered CTAs offering § 4.7 trading programs is limited, but it has been the Commission's experience that such CTAs claiming compliance exemptions in Commission regulation § 4.7 for the purposes of soliciting and serving QEP advisory clients are often large financial institutions with substantial financial assets and advisory experience, or affiliates thereof. Although the Chairman, on behalf of the Commission, certifies under the RFA that the Final Rule will not have a significant impact on a substantial number of small entities, and hereby provides notice of that certification to the Small Business Administration, the Commission nonetheless has determined that publishing a final regulatory flexibility analysis is appropriate to ensure that the impact of the Final Rule is fully addressed. Therefore, the Commission has prepared the following final regulatory flexibility analysis:

i. A Statement of the Need for, and Objectives of, the Rule

As the Commission stated in the Proposal, and as reiterated above in this Final Rule, since the 1992 Final Rule adopting Commission regulation § 4.7, the Commission has witnessed substantial increases in the intermediary population utilizing those exemptions for § 4.7 pools and trading programs offered and available to QEPs. This development also coincides with current commodity interest market conditions, in which the Commission has seen significant expansion and growth in the complexity and diversity of commodity interest products offered via § 4.7 pools and trading programs, which may be more challenging to fully understand. As stated above, the CEA grants the Commission the authority to regulate and register CTAs, as well as to require the maintenance of books and records and filing of reports that the Commission believes is necessary to accomplish its regulatory mission and the goals of the CEA.¹¹⁶ The Commission has determined to adopt the proposed increases to the Portfolio Requirement in the QEP definition,

which will require CTAs to adjust their methods of evaluating prospective advisory clients' QEP status.

ii. A Statement of the Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis, a Statement of the Assessment of the Agency of Such Issues, and a Statement of Any Changes Made in the Proposed Rule as a Result of Such Comments

The Commission received no comments specifically addressing the initial regulatory flexibility analysis published in the Proposal.¹¹⁷ However, the Commission did receive several comments, discussed above, stating that the proposed amendments, if adopted, would prove costly to intermediaries, with such costs being passed down to QEP pool participants and advisory clients, without necessarily resulting in the customer protection benefits the Commission intended. Commenters asserted that the proposed amendments, as applied to common usage scenarios in complex fund structures, may require CTAs to provide QEP Disclosures to entities or persons under common control who likely already receive or have access to such information; that, in other contexts, CTAs have relationships with highly sophisticated and well-resourced QEPs, whose disclosures and access to information are carefully negotiated; and finally, that the proposed amendments would be duplicative of requirements in the securities laws dictating the content and disclosures in Form ADV, which is commonly filed by investment advisers dually registered as CTAs, or of disclosures already being made as a matter of common market practice.

After considering these comments, as well as potential alternatives raised by commenters, the Final Rule does not adopt any minimum disclosure requirements in Commission regulation § 4.7. The Commission will continue evaluating the regulatory alternatives and may adopt further changes in the future. The Commission has determined to adopt the proposed increases to the Portfolio Requirement in the QEP definition as part of this Final Rule, which will require CTAs to adjust their methods of evaluating prospective advisory clients' QEP status. Therefore, the only impact this Final Rule will have on CTAs is with respect to the adoption of the Portfolio Requirement increases that may have a small effect on how CTAs evaluate prospective advisory clients' QEP status.

iii. A Description of and, Where Feasible, an Estimate of the Number of Small Entities to Which the Rule Will Apply

CTAs are generally not subject to any minimum capital requirements, nor does the Commission collect data on the "size" of registered CTAs via Commission registration applications or other required Commission filings or reports. Therefore, the Commission has no data to analyze that would enable it to estimate how many registered CTAs may be considered small entities for RFA purposes. The Commission sought comment on this issue in its initial regulatory flexibility analysis, but received no comments addressing this issue or providing relevant data. It is the Commission's experience that registered CTAs¹¹⁸ claiming Commission regulation § 4.7 exemptions and offering § 4.7 trading programs to QEP advisory clients are frequently large financial institutions offering a variety of trading programs and strategies. Nonetheless, the Commission acknowledges that some percentage or portion of the population of CTAs affected by this Final Rule, *i.e.*, those registered or required to register with the Commission and utilizing the exemptions in Commission regulation § 4.7, may be considered small entities as defined by the RFA, though the Commission lacks the information or data necessary to determine or estimate how many.

iv. A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

The Commission is not adopting the minimum disclosure requirements, or the corresponding proposed recordkeeping, use and amendment requirements, in Commission regulation § 4.7, but is adopting adjustments to the Portfolio Requirement in the QEP definition of that provision. The Commission anticipates that the Final Rule will affect CTAs claiming Commission regulation § 4.7 and offering § 4.7 trading programs, which, as stated above, may include some small entities for RFA purposes. Nonetheless, regardless of whether a CTA is considered a small entity, the Commission believes that all registered CTAs offering and managing § 4.7 trading programs generally possess the

¹¹⁶ 7 U.S.C. 6m, 6n.

¹¹⁷ Proposal, 88 FR 70863–66.

¹¹⁸ As of June 2024, there were approximately 1,241 CTAs registered with the Commission.

professional skills necessary to accurately evaluate the QEP status of prospective advisory clients, which is a baseline requirement for CTAs operating under claimed exemptions in Commission regulation § 4.7, and that the Final Rule will require only minor adjustments to CTAs' existing processes.

v. A Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each One of the Other Significant Alternatives to the Rule Considered by the Agency Which Affect the Impact on Small Entities Was Rejected

The Commission did not propose any specific small entity exemption, but in the initial regulatory flexibility analysis, the Commission identified potential alternatives to the proposed amendments: (1) to not amend Commission regulation § 4.7 to add disclosure requirements for § 4.7 trading programs; (2) to amend Commission regulation § 4.7(c)(1) to require compliance with the entirety of the disclosure regulations generally applicable to registered CTAs offering trading programs to non-QEP advisory clients; or (3) limiting the application of the proposed amendments to registered CTAs claiming Commission regulation § 4.7 and offering § 4.7 trading programs to those CTAs who are not small entities for RFA purposes.

Although the Commission did not receive any comments directly on the initial regulatory flexibility analysis, multiple commenters made suggestions regarding how the Commission might limit the scope of the proposed disclosure requirements, while still accomplishing its customer protection goals with respect to QEPs most in need of regulatory support. In this Final Rule, the Commission has determined to adopt the proposed increases to the Portfolio Requirement in the QEP definition as part of this Final Rule, but is not adopting the proposed minimum disclosure requirements. Nonetheless, the Commission will continue to evaluate regulatory alternatives relating to minimum disclosure requirements and may adopt further changes, in the future, as appropriate.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) imposes certain requirements on Federal agencies, including the Commission, in connection with

conducting or sponsoring any "collection of information" as defined by the PRA.¹¹⁹ Under the PRA, 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 control number from the Office of Management and Budget (OMB). The PRA is intended, in part, to minimize the paperwork burden created for individuals, businesses, and other persons as a result of the collection of information by Federal agencies, and to ensure the greatest possible benefit and utility of information created, collected, maintained, used, shared, and disseminated by or for the Federal Government. The PRA applies to all information, regardless of form or format, whenever the Federal Government is obtaining, causing to be obtained, or soliciting information, and includes required disclosure to third parties or the public, of facts or opinions, when the information collection calls for answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons.

The Final Rule modifies an existing collection of information previously approved by OMB and for which the Commission has received an OMB control number. The title for this collection is "Rules Relating to the Operations and Activities of Commodity Pool Operators and Commodity Trading Advisors and to Monthly Reporting by Futures Commission Merchants" (Collection 3038–0005). Collection 3038–0005 primarily accounts for the burden associated with the Commission's part 4 regulations that concern compliance generally applicable to CPOs and CTAs, as well as certain exemptions from registration as such and exclusions from those definitions, and available relief from compliance with certain regulatory requirements, *e.g.*, Commission regulation § 4.7. In the Proposal, the Commission performed a PRA burden analysis of the proposed amendments and invited the public and other interested parties to comment on any aspect of the information collection requirements discussed therein. The Commission did not receive any such comments. The Commission is revising Collection 3038–0005 to reflect the adoption of the Final Rule amendments to Commission regulation § 4.7, as discussed in further detail below.

Collection 3038–0005 governs responses made pursuant to part 4 of the Commission's regulations, pertaining to

the operations of CPOs and CTAs, including the itemization of compliance burdens remaining after CPOs and CTAs elect certain exemptions from broader compliance obligations in the part 4 regulations. In the NPRM, the Commission proposed new information collection obligations including minimum disclosure requirements and an alternative reporting schedule for required account statements. As discussed above, the Commission is not adopting the minimum disclosure requirements proposed in the NPRM in this Final Rule. The Commission is, however, adopting the amendment addressing the reporting schedule for distribution of account statements by CPOs of § 4.7 pools that are Funds of Funds.

As discussed above, the Commission is adopting an amendment to Commission regulation § 4.7(b)(3) that, consistent with routinely issued Commission exemptive letters, permits CPOs of § 4.7 pools that are Funds of Funds to distribute monthly account statements within 45 days of the month-end, provided that such account statements otherwise meet the requirements of Commission regulation § 4.7(b)(3), and that the CPO notifies its § 4.7 pool participants of this alternate distribution schedule either in the pool's offering memorandum, or upon adoption of this reporting schedule. Collection 3038–0005 currently includes a reporting burden associated with Commission regulation § 4.7(b)(3) that accounts for the quarterly account statements currently required to be distributed by such CPOs to their § 4.7 pools' QEP participants. The Commission is revising the collection to include an additional reporting burden associated with Commission regulation § 4.7(b)(3)(iv), adopted as part of this Final Rule, to account for the burden associated with monthly reporting as an option for § 4.7 pools that are Funds of Funds. As it stated in the NPRM, the Commission believes that "a smaller subset of CPOs and 4.7 pools [will] rely on this reporting schedule, and therefore, burden estimates below are based on 100 CPOs utilizing this alternative monthly account statement schedule for up to three 4.7 pools each."¹²⁰

Accordingly, the aggregate annual estimate for the reporting burden associated with Commission regulation § 4.7(b)(3)(iv), as added by this Final Rule, is as follows:

Estimated number of respondents:
100.

¹¹⁹ 44 U.S.C. 3501, *et seq.*

¹²⁰ *Id.*

Estimated frequency/timing of responses: Monthly.

Estimated number of annual responses per respondent: 36.

Estimated number of annual responses for all respondents: 3,600.

Estimated annual burden hours per response: 1.

Estimated total annual burden hours per respondent: 36.

Estimated total annual burden hours for all respondents: 3,600.

C. Cost-Benefit Considerations

1. Statutory and Regulatory Background

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its discretionary actions before promulgating a regulation under the CEA or issuing certain orders. CEA section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission may, in its discretion, give greater weight to any of the five enumerated areas of concern, and may, in its discretion, determine that, notwithstanding its costs, a particular rule is necessary or appropriate to protect the public interest, or to effectuate any of the provisions, or to accomplish any of the purposes, of the CEA. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors.

The Commission invited public comment on the cost-benefit consideration in the Proposal. There were several general comments that it was “inadequate.”¹²¹ One commenter stated that they believed the Commission failed to engage in an adequate cost-benefit analysis sufficient to justify a burdensome and costly disclosure regime.¹²² Similarly, another commenter stated that they believed the cost-benefit analysis in the Proposal was insufficient.¹²³ This commenter further encouraged the Commission to “carefully evaluate the increased operational costs associated with requiring CPOs and CTAs offering 4.7 pools and managed account programs to

provide the proposed additional disclosures,” as they “will almost certainly be passed on to the pools’ participants and managed account programs’ clients.”¹²⁴ Despite these general objections to the Commission’s Proposal, commenters provided no additional detail regarding how or why the Commission’s preliminary cost-benefit analysis was “inadequate,” nor did commenters respond to the Commission’s specific requests for comment associated with the Proposal’s cost-benefit considerations discussion,¹²⁵ both of which impede the Commission’s ability to remediate the deficiencies commenters perceived in the Proposal’s cost-benefit analysis. Regardless, as detailed below, the Commission has considered the broad criticism asserted by commenters, as well as the adjustments made from the proposed amendments to those in this Final Rule.

As discussed above, the Commission is adopting amendments to Commission regulation § 4.7 that will result in additional costs for CPOs and CTAs operating § 4.7 pools and trading programs. In response to certain comments, however, the Commission is declining to finalize the proposed minimum disclosure requirements and believes it appropriate to spend additional time considering the alternative proposals put forward by commenters. The Commission believes this approach will significantly reduce the costs and burdens to § 4.7 CPOs and CTAs arising from this Final Rule, as compared to those outlined in the NPRM. The Final Rule will, however, finalize the proposed amendments that will (1) increase the Portfolio Requirement in Commission regulation § 4.7 such that persons required to meet it to be a QEP may satisfy it by either: (a) owning securities and other assets worth at least \$4,000,000; (b) having on deposit with an FCM for their own account at least \$400,000 in initial margin, option premiums, or minimum security deposits; or (c) owning a portfolio of funds and assets that, when expressed as percentages of the prior two thresholds, have a combined value of at least 100%; and (2) add a provision to Commission regulation § 4.7(b)(3) codifying routinely issued exemptive letters allowing CPOs of § 4.7 pools that are Funds of Funds to distribute account

statements on a monthly basis, within 45 days of the end of the month-end. These regulatory amendments adopted by the Final Rule will likely generate minimal costs to § 4.7 CPOs and CTAs, but are expected to result in several benefits to intermediaries and pool participants and advisory clients. The baseline against which these costs and benefits are compared is the regulatory status quo set forth in current Commission regulation § 4.7. The Commission has endeavored to enumerate material costs and benefits and, when reasonably feasible, assign a quantitative value to them. Where it is not reasonably feasible to quantify costs and benefits of the proposed amendments, those costs and benefits are discussed qualitatively.

The consideration of costs and benefits below is based on the understanding that the markets function internationally, with many transactions involving U.S. firms taking place across international boundaries; with some Commission registrants being organized outside of the United States; with some leading industry members typically conducting operations both within and outside the United States; and with industry members commonly following substantially similar business practices wherever located. Where the Commission does not specifically refer to matters of location, the discussion of costs and benefits below refers to the effects of this Final Rule on all activity subject to the amended regulations, whether by virtue of the activity’s physical location in the United States or by virtue of the activity’s connection with or effect on U.S. commerce under CEA section 2(i). Some CPOs and CTAs are located outside of the United States.

2. Increasing Financial Thresholds in the Portfolio Requirement of the “Qualified Eligible Person” Definition

The Final Rule increases the Portfolio Requirement in Commission regulation § 4.7 such that persons required to meet the Portfolio Requirement to be considered QEPs can do so by either: (1) owning securities and other assets worth at least \$4,000,000; (2) having on deposit with an FCM for their own account at least \$400,000 in initial margin, option premiums, or minimum security deposits; or (3) owning a portfolio of funds and assets that, when expressed as percentages of the prior two thresholds, have a combined value of at least 100%. The Commission did not receive any specific comments regarding whether any costs associated with the Portfolio Requirement financial thresholds would change as a result of the proposed increases. As stated in the

¹²¹ MFA Letter, at 12; SIFMA AMG Letter, at 10; and AIMA Letter, at 8.

¹²² MFA Letter, at 12. However, in their comment letter, MFA did not provide any specific cost considerations or analysis for the Commission to consider.

¹²³ SIFMA AMG Letter, at 10.

¹²⁴ *Id.*

¹²⁵ See, e.g., Proposal, 88 FR 70872 (inquiring as to “the costs of gathering and disseminating the other types of information required to be included in the QEP Disclosures,” and “how . . . fees and expenses charged by CPOs and CTAs . . . [would] be affected by the proposed disclosure requirements”).

Proposal and herein, the Portfolio Requirement was adopted to identify prospective pool participants and advisory clients that possess sufficient financial experience and sophistication to withstand the risks associated with their participation in the commodity interest markets without the full panoply of protections afforded under part 4 of the Commission's regulations. As stated previously in this release and in the Proposal, the Commission believes that increasing such thresholds appropriately restores the alignment of Commission regulation § 4.7 with the Commission's original intention when it was adopted in 1992 to differentiate between retail investors and more sophisticated market participants, *i.e.*, QEPs.

The Commission recognizes, as it did in the Proposal, that increasing the thresholds in the Portfolio Requirement will result in some subset of QEPs no longer qualifying as such, which, should such newly designated non-QEPs still desire to participate in the commodity interest markets, could result in market forces supporting the development and offering of additional non-§ 4.7 pools and trading strategies. This would result in more diverse offerings to retail commodity interest market participants, thereby enhancing the variety and vibrancy of the non-QEP marketplace. As stated in the Proposal, the Commission believes that this development would result in more non-QEPs having the opportunity to participate in the commodity interest markets through commodity pools and trading programs better aligned with their particular risk tolerances and investment goals.

As noted in the Proposal, due to the increases in the Portfolio Requirement thresholds, § 4.7 CPOs will likely no longer be able to offer pool participation units to certain QEPs who will no longer qualify under the new thresholds adopted herein. Such CPOs, as well as some § 4.7 CTAs, may decide to offer commodity pools and trading programs that are subject to the full suite of requirements under part 4 of the Commission's regulations, which necessarily would result in increased costs associated with compliance. Conversely, it is possible that some CPOs and CTAs may continue to find the compliance relief provided by Commission regulation § 4.7 to outweigh possible gains to be had by accessing the non-QEP market, which would mitigate the potential benefit to non-QEPs. Additionally, the Commission expects there to be certain ministerial costs associated with system updates required for § 4.7 CPOs and

CTAs to implement the increased thresholds, but given that the general requirements associated with the Portfolio Requirement are not changing in a substantive way beyond the actual numerical value of the thresholds, the Commission does not expect such costs to be significant.

Section 15(a) Factors

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of the amendments to Commission regulation § 4.7 with respect to the following factors: protection of market participants and the public; efficiency, competitiveness, and financial integrity of markets; price discovery; sound risk management practices; and other public interest considerations. As discussed above, the Final Rule's amendments increasing the financial thresholds in the Portfolio Requirement will, in the Commission's opinion, more closely align the QEP definition with the original intent of the regulation, which is to assure that offerings operated pursuant to Commission regulation § 4.7 compliance exemptions are only made to persons with "substantial investment experience and thus a high degree of sophistication with regard to investments as well as financial resources to withstand the risk of their investments."¹²⁶

a. Protection of Market Participants and the Public

As stated above, the Commission believes that this amendment will benefit the commodity interest markets and the general public by realigning financial thresholds in its most commonly used regulations in a manner that accounts for the impacts of inflation since their original adoption and more accurately reflects current economic circumstances; the Commission expects that this will result in persons investing in commodity interest products offered by registered CPOs and CTAs being more accurately categorized as QEPs, and thus, more appropriately limited in their investment choices. Moreover, raising the Portfolio Requirement thresholds, as a practical matter, will likely limit the prospective investor population for § 4.7 pools and trading programs to a smaller number of persons. To the extent persons who meet the higher Portfolio Requirement thresholds are more financially sophisticated or resilient than those who no longer qualify, this amendment should result in individuals and entities, both QEPs and non-QEPs, being

offered pools and trading programs that are regulated in a manner commensurate with their respective needs for customer protection. If the increased thresholds further lead to the creation of more commodity pools and trading programs subject to the full part 4 compliance requirements by registered CPOs and CTAs, this too will potentially lead to greater transparency in their activities, which also protects persons investing in commodity interest products. Additionally, greater variety in the commodity pools and trading programs available to non-QEPs will provide more options for this population to consider, which may further enable them to make more appropriate investment decisions by choosing the offerings best suited to their individual risk appetite or other portfolio needs.

b. Efficiency, Competitiveness, and Financial Integrity of Markets

The Final Rule's amendments to the Portfolio Requirement may also affect the size, composition, or number of commodity pools and trading programs in the commodity interest markets, especially those offered solely to QEPs. This may, in turn, affect the flow of investing in commodity interests. The financial economics literature suggests that, to the extent changing the QEP definition reduces the flow of non-commercial funds into commodity interest markets, the cost to commercial traders using futures markets to hedge their risks may increase.¹²⁷ Via this mechanism, the Final Rule's amendment may have an indirect effect on efficiency of the futures markets with respect to the hedging costs of operating companies, commodity producers, or other commercial traders.

c. Price Discovery

The increased Portfolio Requirement thresholds are likely to result in fewer persons being considered QEPs, which may further result in fewer participants and clients in offered pools and trading programs operated under Commission regulation § 4.7. An additional indirect effect of the Final Rule's amendments could be a change in the flow of investment in commodity interests by non-commercial traders. The financial economics literature has found ambiguous results regarding the relationship between increased investment by non-commercial traders in commodity interest markets and price

¹²⁶ 1992 Final Rule, 57 FR 34854 (citing and quoting 1992 Proposal, 57 FR 3151).

¹²⁷ Goldstein and Yang, "Commodity Financialization and Information Transmission," 2022, *Journal of Finance*, 77, 2613–2668.

discovery.¹²⁸ As such, it is difficult to *ex ante* predict how changes in the Portfolio Requirement thresholds would impact price discovery.

d. Sound Risk Management Practices

Increasing the Portfolio Requirement thresholds may result in registered CPOs and CTAs that previously only offered pools and trading programs to QEPs creating and offering pools and trading programs designed for persons that are not QEPs. Consequently, these non-QEP pools and trading programs operated by registered CPOs and CTAs would then be subject to the full complement of part 4 compliance requirements, which could result in more diligent risk management practices by the CPOs and CTAs.

e. Other Public Interest Considerations

The original Portfolio Requirement thresholds in the QEP definition were intended to ensure that only persons possessing an appropriate and high level of trading experience, acumen, and financial resources would be eligible to invest in complex commodity interest investments offered and operated under Commission regulation § 4.7. The Commission determined it appropriate to lessen the compliance burdens for registered CPOs and CTAs limiting their prospective participants and clients to financially sophisticated QEPs through the exemptions provided by Commission regulation § 4.7 for their § 4.7 pools and trading programs. The 1992 Portfolio Requirement thresholds were adopted to provide a metric by which CPOs and CTAs could approximately assess the experience and financial wherewithal of potential pool participants or advisory clients, ensuring that they truly possess the sophistication and resilience of other QEPs not subject to such thresholds. Updating these thresholds to account for inflation realigns the Portfolio Requirement with the original intent of the QEP definition and modernizes its provisions consistent with today's economic circumstances.

3. Permitting Monthly Account Statements Consistent With Commission Exemptive Letters for Certain § 4.7 Pools

Consistent with longstanding exemptive letter relief described herein, the Final Rule adds a provision to Commission regulation § 4.7(b)(3) allowing CPOs of § 4.7 pools that are Funds of Funds to distribute account statements on a monthly basis, within 45 days of the month-end, provided that

such CPOs notify their pool participants. The Commission received no comments addressing any costs that § 4.7 CPOs or CTAs may incur as a result of adopting this amendment.

As discussed in the Proposal, the primary benefit of this amendment is to facilitate § 4.7 pools' investment in other pools or collective investment vehicles without potentially violating the periodic reporting requirements in Commission regulation § 4.7. The Commission expects that this would allow CPOs of § 4.7 pools to seek higher returns and/or better diversification for their participants by investing in other pools or other collective investment vehicles, without requiring an exemptive letter to ensure they can meet their periodic reporting requirements, or otherwise risking chronic compliance violations. The Commission also continues to believe there is significant benefit to be gained by adopting this amendment because CPOs of § 4.7 Fund of Funds pools will be able to adopt an alternative account statement schedule at their convenience or immediately when necessary, rather than being required to seek an exemptive letter individually from the Commission and to potentially delay operational decisions or changes until such letter is received. Moreover, the Final Rule also ensures that similarly situated registrants are treated in a consistent manner by making the alternative schedule available to all qualifying CPOs and § 4.7 pools without the need for individual requests.

Under the alternative schedule, as described above, qualifying CPOs would be required to prepare and distribute periodic account statements on a monthly basis, which is more frequent than the baseline of quarterly. This will result in increased administrative costs to CPOs that elect this alternative schedule associated with the monthly account statements, which may be passed on to their pool participants. Under the terms of the Final Rule, qualifying CPOs are also required to disclose to their pool participants their election to use the alternative account statement schedule, and this disclosure must be provided to their prospective and existing pool participants. The notification requirement will also result in costs to the CPO, and potentially the pool participants, which will vary in amount depending on whether the CPO chooses to incorporate the notice in an existing communication to pool participants or to create a new standalone disclosure. Similarly, the costs associated with dissemination will vary depending on whether the offered pool is still accepting new participants,

or if it is closed, as the Commission does not expect § 4.7 CPOs to prepare disclosures for pool participants with respect to pool participation units purchased prior to the effective date of this Final Rule. The Commission notes that this alternative reporting schedule is voluntary, and therefore, should a CPO determine that the costs associated with more frequent statements outweighs the benefits associated with adopting the alternative schedule, it is not required to do so and can continue to provide quarterly account statements within 30 days of the quarter-end, as currently required under Commission regulation § 4.7 (and which will remain unchanged by this Final Rule).

The Commission expects that CPOs will use the services of an accountant to prepare the monthly account statements permitted by the Final Rule amendments. The BLS states that the mean wage for accountants as of May 2023, the most recent information available, is \$43.65 per hour.¹²⁹ The Commission has estimated that the time burden associated with complying with the alternate schedule for periodic account statements required under the Final Rule is 36 hours per CPO. If the CPO solely uses the services of an accountant to complete these tasks, the total cost associated with the alternative account statement provisions adopted herein is \$1,571.40 per CPO.

Section 15(a) Factors

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of the amendment to Commission regulation § 4.7(b)(3) with respect to the following factors: protection of market participants and the public; efficiency, competitiveness, and financial integrity of markets; price discovery; sound risk management practices; and other public interest considerations. As discussed above, the addition to Commission regulation § 4.7(b)(3) of a permissible monthly account statement schedule will facilitate compliance with periodic reporting deadlines for CPOs of § 4.7 Fund of Funds pools. Absent this change (and assuming such § 4.7 pool has received no exemptive letter from the Commission), it may otherwise be impractical for such § 4.7 pools to operate as Funds of Funds, due to the baseline applicable quarterly reporting requirements in Commission regulation § 4.7.

¹²⁹ Bureau of Labor Statistics, United States Department of Labor, Occupational Employment and Wage Statistics, Accountants and Auditors, May 2023 (published April 2024), available at <https://www.bls.gov/oes/current/oes132011.htm>.

¹²⁸ *Id.*

a. Protection of Market Participants and the Public

As discussed above, the Final Rule will permit CPOs of § 4.7 Fund of Funds pools to adopt an alternative monthly account statement schedule, provided such statements are distributed within 45 days of the end of each month, and provided that they notify their QEP pool participants of such reporting schedule. To the extent this amendment encourages QEPs to participate in § 4.7 Fund of Funds pools, rather than other § 4.7 pools, it may require them to adjust to a different account statement schedule, but the Commission believes, based on its past observation of the implementation of staff letters that have been issued addressing this issue, that this amendment will likely provide such QEPs with more complete and accurate account statements on a more frequent basis. Additionally, the Final Rule may facilitate the formation of § 4.7 Fund of Funds pools by making it easier for their CPOs to comply with the applicable periodic reporting requirements under Commission regulation § 4.7; this trend may also serve to benefit QEP participants, in that the CPOs of § 4.7 Fund of Funds pools may be able to operate them in a manner that achieves exposure to a wider variety of underlying investment strategies through their investee pools, while continuing to remain compliant with their regulatory obligations. Finally, such CPOs will also have greater incentive and may possess more resources to monitor the behavior of their § 4.7 Fund of Funds pools' underlying investments in other pools or funds, than QEPs directly investing therein.

b. Efficiency, Competitiveness, and Financial Integrity of Markets

The Final Rule amending Commission regulation § 4.7(b)(3) may indirectly affect the functioning of commodity interest markets. To the extent that the Final Rule affects the behavior of CPOs or the size and composition of their § 4.7 Fund of Funds pools, it might also affect the flow of investing in commodity interests. The financial economics literature suggests that increased investment by non-commercial traders in commodity interest markets will generally reduce the difference between futures prices and expected future spot prices.¹³⁰ This effect means that, to the extent that offering an alternative schedule for periodic reporting in § 4.7 Fund of

Funds pools increases the flow of non-commercial funds into commodity interest markets, it will tend to also reduce the cost to commercial traders of using the futures market to hedge their risks. In that sense, this Final Rule may have an indirect effect on efficiency of the futures markets in regard to the hedging costs of operating companies, commodity producers, or other commercial market participants.

c. Price Discovery

To the extent that the Final Rule amending Commission regulation § 4.7(b)(3) affects the size or composition of § 4.7 pools, it might also affect the flow of investing in commodity interests. The financial economics literature has found ambiguous results regarding the relationship between increased investment by non-commercial traders in commodity interest markets and commodity price discovery.¹³¹ As such, it is difficult for the Commission to *ex ante* predict how the addition of an alternative account statement schedule for § 4.7 Fund of Funds pools would impact price discovery.

d. Sound Risk Management Practices

Periodic reporting requirements in the form of regular account statements provided to pool participants serve as an effective means for participants as well as CPOs to monitor pools' risk management. Because the amount of funds a CPO manages through its operated pools is likely responsive to its past performance,¹³² requiring the provision of complete financial information on pool performance through regular account statements can serve to provide an incentive for sound risk management by such CPOs. As discussed above, the Final Rule amending Commission regulation § 4.7(b)(3) may encourage the formation of § 4.7 Fund of Funds pools, whose CPOs may be better able to monitor the performance of underlying commodity pools or funds in which they invest, as compared to QEP participants investing directly therein. This also may positively influence CPOs' risk management practices in their pools, to the extent their participants are other § 4.7 pools.

e. Other Public Interest Considerations

A key practical consideration is that, absent exemptive letters issued by the

Commission, the existing Commission regulation § 4.7(b)(3) appears to make it very difficult for CPOs to operate their § 4.7 pools as Funds of Funds, while complying with applicable periodic reporting requirements. To the extent that facilitating the operation of such § 4.7 pools as Funds of Funds is a legitimate policy goal of the Commission (as suggested by its routine granting of exemptive letters on this topic), changing the regulations to explicitly permit this alternative account statement schedule will be a more effective and direct means of accomplishing that objective that further ensures more consistent treatment of similarly situated registrants.

D. Antitrust Considerations

Section 15(b) of the CEA requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the purposes of the CEA in issuing any order or adopting any Commission rule or regulation.¹³³ The Commission believes that the public interest to be protected by the antitrust laws is generally to protect competition. In the Proposal, the Commission requested comment on whether the NPRM implicated any other specific public interest to be protected by the antitrust laws, but received no comments.

The Commission has considered the amendments in this Final Rule to determine whether they are anticompetitive and has not identified any anticompetitive effects. Because the Commission has not determined that the Final Rule is anticompetitive or has anticompetitive effects, the Commission has not identified any less anticompetitive means of achieving the purposes of the CEA.

List of Subjects

17 CFR Part 1

Brokers, Commodity futures, Consumer protection, Reporting and recordkeeping requirements.

17 CFR Part 3

Administrative practice and procedure, Commodity futures, Consumer protection, Definitions, Foreign futures, Foreign options, Registration requirements.

17 CFR Part 4

Advertising, Brokers, Commodity futures, Commodity pool operators, Commodity trading advisors, Consumer

¹³¹ *Id.*

¹³² Sirra and Tufano, "Costly Search and Mutual Fund Flows," *Journal of Finance*, 1998, 53, 1589–1622; Del Guercio and Reuter, "Mutual Fund Performance and the Incentive to Generate Alpha," *Journal of Finance*, 2014, 1673–1704.

¹³⁰ Goldstein and Yang, "Commodity Financialization and Information Transmission," 2022, *Journal of Finance*, 77, 2613–2668.

¹³³ 7 U.S.C. 19(b).

protection, Reporting and recordkeeping requirements.

17 CFR Part 30

Consumer protection, Fraud.

17 CFR Part 43

Consumer protection, Reporting and recordkeeping requirements, Swaps.

17 CFR Part 75

Banks, Banking, Compensation, Credit, Derivatives, Federal branches and agencies, Federal savings associations, Government securities, Hedge funds, Insurance, Investments, National banks, Penalties, Proprietary trading, Reporting and recordkeeping requirements, Risk, Risk retention, Securities, Swap dealers, Trusts and trustees, Volcker rule.

For the reasons stated in the preamble, the Commodity Futures Trading Commission amends 17 CFR chapter I as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

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

Authority: 7 U.S.C. 1a, 2, 5, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6l, 6m, 6n, 6o, 6p, 6r, 6s, 7, 7a–1, 7a–2, 7b, 7b–3, 8, 9, 10a, 12, 12a, 12c, 13a, 13a–1, 16, 16a, 19, 21, 23, and 24 (2012).

■ 2. In § 1.35, revise paragraph (b)(5)(i)(D) to read as follows:

§ 1.35 Records of commodity interest and related cash or forward transactions.

* * * * *

(b) * * *

(5) * * *

(i) * * *

(D) A foreign adviser that exercises discretionary trading authority solely over the accounts of non-U.S. persons, as defined in § 4.7(a)(4) of this chapter;

* * * * *

PART 3—REGISTRATION

■ 3. The authority citation for part 3 continues to read as follows:

Authority: 5 U.S.C. 552, 552b; 7 U.S.C. 1a, 2, 6a, 6b, 6b–1, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6m, 6n, 6o, 6p, 6s, 8, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21, and 23.

■ 4. In § 3.10, revise the introductory text of paragraph (c)(5)(ii) to read as follows:

§ 3.10 Registration of futures commission merchants, retail foreign exchange dealers, introducing brokers, commodity trading advisors, commodity pool operators, swap dealers, major swap participants and leverage transaction merchants.

* * * * *

(c) * * *

(5) * * *

(ii) With respect to paragraph (c)(5)(i) of this section, initial capital contributed to a commodity pool by an affiliate, as defined by § 4.7(a)(1) of this chapter, of the pool's commodity pool operator shall not be considered for purposes of determining whether such commodity pool operator is executing commodity interest transactions on behalf of a commodity pool, the participants of which are all foreign located persons; *provided*, that:

* * * * *

PART 4—COMMODITY POOL OPERATORS AND COMMODITY TRADING ADVISORS

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

Authority: 7 U.S.C. 1a, 2, 6(c), 6b, 6c, 6l, 6m, 6n, 6o, 12a, and 23.

■ 6. In § 4.7:

■ a. Revise paragraph (a);

■ b. Add paragraph (b)(3)(iv); and

■ c. Revise paragraph (b)(5).

The revisions and addition read as follows:

§ 4.7 Exemption from certain part 4 requirements for commodity pool operators with respect to offerings to qualified eligible persons and for commodity trading advisors with respect to advising qualified eligible persons.

* * * * *

(a) *Definitions.* (1) *Affiliate* of, or a person *affiliated* with, a specified person means a person that directly or indirectly through one or more persons, controls, is controlled by, or is under common control with the specified person.

(2) *Exempt account* means the account of a qualified eligible person that is directed or guided by a commodity trading advisor pursuant to an effective claim for exemption under this section.

(3) *Exempt pool* means a pool that is operated pursuant to an effective claim for exemption under this section.

(4) *Non-United States person* means:

(i) A natural person who is not a resident of the United States;

(ii) A partnership, corporation or other entity, other than an entity organized principally for passive investment, organized under the laws of a foreign jurisdiction and which has its principal place of business in a foreign jurisdiction;

(iii) An estate or trust, the income of which is not subject to United States income tax regardless of source;

(iv) An entity organized principally for passive investment such as a pool,

investment company or other similar entity; *Provided*, That units of participation in the entity held by persons who do not qualify as Non-United States persons or otherwise as qualified eligible persons represent in the aggregate less than 10% of the beneficial interest in the entity, and that such entity was not formed principally for the purpose of facilitating investment by persons who do not qualify as Non-United States persons in a pool with respect to which the operator is exempt from certain requirements of this part by virtue of its participants being Non-United States persons; and

(v) A pension plan for the employees, officers or principals of an entity organized and with its principal place of business outside the United States.

(5) *Portfolio Requirement* means that a person:

(i) Owns securities (including pool participations) of issuers not affiliated with such person and other investments with an aggregate market value of at least \$4,000,000;

(ii) Has had on deposit with a futures commission merchant, for its own account at any time during the six-month period preceding either the date of sale to that person of a pool participation in the exempt pool or the date that the person opens an exempt account with the commodity trading advisor, at least \$400,000 in exchange-specified initial margin and option premiums, together with any required minimum security deposits for retail forex transactions (defined in § 5.1(m) of this chapter), for commodity interest transactions; or

(iii) Owns a portfolio comprised of a combination of the funds or property specified in paragraphs (a)(5)(i) and (ii) of this section, in which the sum of the funds or property includable under paragraph (a)(5)(i) of this section, expressed as a percentage of the minimum amount required thereunder, and the amount of initial margin, option premiums, and minimum security deposits includable under paragraph (a)(5)(ii) of this section, expressed as a percentage of the minimum amount required thereunder, equals at least one hundred percent. An example of a composite portfolio acceptable under this paragraph (a)(5)(iii) would consist of \$2,000,000 in securities and other property (50% of paragraph (a)(5)(i)) and \$200,000 in initial margin, option premiums, and minimum security deposits (50% of paragraph (a)(5)(ii)).

(6) *Qualified eligible person* means any person, acting for its own account or for the account of a qualified eligible person, who the commodity pool

operator reasonably believes, at the time of the sale to that person of a pool participation in the exempt pool, or who the commodity trading advisor reasonably believes, at the time that person opens an exempt account, is included in the following list of persons that is divided into two categories: Persons who are not required to satisfy the Portfolio Requirement defined in paragraph (a)(5) of this section to be qualified eligible persons, and those persons who must satisfy the Portfolio Requirement in paragraph (a)(5) to be qualified eligible persons.

(i) *Persons who need not satisfy the Portfolio Requirement to be qualified eligible persons.* (A) A futures commission merchant registered pursuant to section 4d of the Act, or a principal thereof;

(B) A retail foreign exchange dealer registered pursuant to section 2(c)(2)(B)(i)(II)(gg) of the Act, or a principal thereof;

(C) A swap dealer registered pursuant to section 4s(a)(1) of the Act, or a principal thereof;

(D) A broker or dealer registered pursuant to section 15 of the Securities Exchange Act of 1934, or a principal thereof;

(E) A commodity pool operator registered pursuant to section 4m of the Act, or a principal thereof; *Provided*, That the pool operator:

(1) Has been registered and active as such for two years; or

(2) Operates pools which, in the aggregate, have total assets in excess of \$5,000,000;

(F) A commodity trading advisor registered pursuant to section 4m of the Act, or a principal thereof; *Provided*, That the trading advisor:

(1) Has been registered and active as such for two years; or

(2) Provides commodity interest trading advice to commodity accounts which, in the aggregate, have total assets in excess of \$5,000,000 deposited at one or more futures commission merchants;

(G) An investment adviser registered pursuant to section 203 of the Investment Advisers Act of 1940 ("Investment Advisers Act") or pursuant to the laws of any state, or a principal thereof; *Provided*, That the investment adviser:

(1) Has been registered and active as such for two years; or

(2) Provides securities investment advice to securities accounts which, in the aggregate, have total assets in excess of \$5,000,000 deposited at one or more registered securities brokers;

(H) A "qualified purchaser" as defined in section 2(a)(51)(A) of the

Investment Company Act of 1940 ("Investment Company Act");

(I) A "knowledgeable employee" as defined in § 270.3c-5 of this title;

(J) With respect to an exempt pool:

(1) The commodity pool operator, commodity trading advisor or investment adviser of the exempt pool offered or sold, or an affiliate of any of the foregoing;

(2) A principal of the exempt pool or the commodity pool operator, commodity trading advisor or investment adviser of the exempt pool, or an affiliate of any of the foregoing;

(3) An employee of the exempt pool or the commodity pool operator, commodity trading advisor or investment adviser of the exempt pool, or of an affiliate of any of the foregoing (other than an employee performing solely clerical, secretarial or administrative functions with regard to such person or its investments) who, in connection with his or her regular functions or duties, participates in the investment activities of the exempt pool, other commodity pools operated by the pool operator of the exempt pool or other accounts advised by the trading advisor or the investment adviser of the exempt pool, or by the affiliate; *Provided*, That such employee has been performing such functions and duties for or on behalf of the exempt pool, pool operator, trading advisor, investment adviser or affiliate, or substantially similar functions or duties for or on behalf of another person engaged in providing commodity interest, securities or other financial services, for at least 12 months;

(4) Any other employee of, or an agent engaged to perform legal, accounting, auditing or other financial services for, the exempt pool or the commodity pool operator, commodity trading advisor or investment adviser of the exempt pool, or any other employee of, or agent so engaged by, an affiliate of any of the foregoing (other than an employee or agent performing solely clerical, secretarial or administrative functions with regard to such person or its investments); *Provided*, That such employee or agent:

(i) Is an accredited investor as defined in § 230.501(a)(5) or (6) of this title; and

(ii) Has been employed or engaged by the exempt pool, commodity pool operator, commodity trading advisor, investment adviser or affiliate, or by another person engaged in providing commodity interest, securities or other financial services, for at least 24 months;

(5) The spouse, child, sibling or parent of a person who satisfies the

criteria of paragraph (a)(6)(i)(J)(1), (2), (3), or (4) of this section; *Provided*, That:

(i) An investment in the exempt pool by any such family member is made with the knowledge and at the direction of the person; and

(ii) The family member is not a qualified eligible person for the purposes of paragraph (a)(6)(ii)(K) of this section;

(6) Any person who acquires a participation in the exempt pool by gift, bequest or pursuant to an agreement relating to a legal separation or divorce from a person listed in paragraph (a)(6)(i)(J)(1), (2), (3), (4), or (5) of this section;

(7) The estate of any person listed in paragraph (a)(6)(i)(J)(1), (2), (3), (4), or (5) of this section; or

(8) A company established by any person listed in paragraph (a)(6)(i)(J)(1), (2), (3), (4), or (5) of this section exclusively for the benefit of (or owned exclusively by) that person and any person listed in paragraph (a)(6)(i)(J)(6) or (7) of this section;

(K) With respect to an exempt account:

(1) An affiliate of the commodity trading advisor of the exempt account;

(2) A principal of the commodity trading advisor of the exempt account or of an affiliate of the commodity trading advisor;

(3) An employee of the commodity trading advisor of the exempt account or of an affiliate of the trading advisor (other than an employee performing solely clerical, secretarial or administrative functions with regard to such person or its investments) who, in connection with his or her regular functions or duties, participates in the investment activities of the trading advisor or the affiliate; *Provided*, That such employee has been performing such functions and duties for or on behalf of the trading advisor or the affiliate, or substantially similar functions or duties for or on behalf of another person engaged in providing commodity interest, securities or other financial services, for at least 12 months;

(4) Any other employee of, or an agent engaged to perform legal, accounting, auditing or other financial services for, the commodity trading advisor of the exempt account or any other employee of, or agent so engaged by, an affiliate of the trading advisor (other than an employee or agent performing solely clerical, secretarial or administrative functions with regard to such person or its investments); *Provided*, That such employee or agent:

(i) Is an accredited investor as defined in § 230.501(a)(5) or (6) of this title; and

(ii) Has been employed or engaged by the commodity trading advisor or the affiliate, or by another person engaged in providing commodity interest, securities or other financial services, for at least 24 months;

(5) The spouse, child, sibling or parent of the commodity trading advisor of the exempt account or of a person who satisfies the criteria of paragraph (a)(6)(i)(K)(1), (2), (3), or (4) of this section; *Provided*, That:

(i) The establishment of an exempt account by any such family member is made with the knowledge and at the direction of the person; and

(ii) The family member is not a qualified eligible person for the purposes of paragraph (a)(6)(ii)(K) of this section;

(6) Any person who acquires an interest in an exempt account by gift, bequest or pursuant to an agreement relating to a legal separation or divorce from a person listed in paragraph (a)(6)(i)(K)(1), (2), (3), (4), or (5) of this section;

(7) The estate of any person listed in paragraph (a)(6)(i)(K)(1), (2), (3), (4), or (5) of this section; or

(8) A company established by any person listed in paragraph (a)(6)(i)(K)(1), (2), (3), (4), or (5) of this section exclusively for the benefit of (or owned exclusively by) that person and any person listed in paragraph (a)(6)(i)(K)(6) or (7) of this section;

(L) A trust; *Provided*, That:

(1) The trust was not formed for the specific purpose of either participating in the exempt pool or opening an exempt account; and

(2) The trustee or other person authorized to make investment decisions with respect to the trust, and each settlor or other person who has contributed assets to the trust, is a qualified eligible person;

(M) An organization described in section 501(c)(3) of the Internal Revenue Code (the "IRC"); *Provided*, That the trustee or other person authorized to make investment decisions with respect to the organization, and the person who has established the organization, is a qualified eligible person;

(N) A Non-United States person;

(O) An entity in which all of the unit owners or participants, other than the commodity trading advisor claiming relief under this section, are qualified eligible persons;

(P) An exempt pool; or

(Q) Notwithstanding paragraph (a)(6)(ii) of this section, an entity as to which a notice of eligibility has been filed pursuant to § 4.5 which is operated in accordance with such rule and in which all unit owners or participants,

other than the commodity trading advisor claiming relief under this section, are qualified eligible persons.

(ii) *Persons who must satisfy the Portfolio Requirement to be qualified eligible persons.* With respect to the persons listed in paragraphs (a)(6)(ii)(A) through (L) of this section, the commodity pool operator must reasonably believe, at the time of the sale to such person of a participation in the exempt pool, or the commodity trading advisor must reasonably believe, at the time such person opens an exempt account, that such person satisfies the Portfolio Requirement in paragraph (a)(5) of this section:

(A) An investment company registered under the Investment Company Act or a business development company as defined in section 2(a)(48) of such Act not formed for the specific purpose of either investing in the exempt pool or opening an exempt account;

(B) A bank as defined in section 3(a)(2) of the Securities Act of 1933 (the "Securities Act") or any savings and loan association or other institution as defined in section 3(a)(5)(A) of the Securities Act acting for its own account or for the account of a qualified eligible person;

(C) An insurance company as defined in section 2(13) of the Securities Act acting for its own account or for the account of a qualified eligible person;

(D) A plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of \$5,000,000;

(E) An employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974; *Provided*, That the investment decision is made by a plan fiduciary, as defined in section 3(21) of such Act, which is a bank, savings and loan association, insurance company, or registered investment adviser; or that the employee benefit plan has total assets in excess of \$5,000,000; or, if the plan is self-directed, that investment decisions are made solely by persons that are qualified eligible persons;

(F) A private business development company as defined in section 202(a)(22) of the Investment Advisers Act;

(G) An organization described in section 501(c)(3) of the IRC, with total assets in excess of \$5,000,000;

(H) A corporation, Massachusetts or similar business trust, or partnership, limited liability company or similar business venture, other than a pool,

which has total assets in excess of \$5,000,000, and is not formed for the specific purpose of either participating in the exempt pool or opening an exempt account;

(I) A natural person whose individual net worth, or joint net worth with that person's spouse, at the time of either his purchase in the exempt pool or his opening of an exempt account would qualify him as an accredited investor as defined in § 230.501(a)(5) of this title;

(J) A natural person who would qualify as an accredited investor as defined in § 230.501(a)(6) of this title;

(K) A pool, trust, insurance company separate account or bank collective trust, with total assets in excess of \$5,000,000, not formed for the specific purpose of either participating in the exempt pool or opening an exempt account, and whose participation in the exempt pool or investment in the exempt account is directed by a qualified eligible person; or

(L) Except as provided for the governmental entities referenced in paragraph (a)(6)(ii)(D) of this section, if otherwise authorized by law to engage in such transactions, a governmental entity (including the United States, a state, or a foreign government) or political subdivision thereof, or a multinational or supranational entity or an instrumentality, agency, or department of any of the foregoing.

(7) *United States* means the United States, its states, territories or possessions, or an enclave of the United States government, its agencies or instrumentalities.

(b) * * *

(3) * * *

(iv) Where the exempt pool is invested in one or more other pools or funds operated by third parties, the commodity pool operator may choose instead to prepare and distribute to its pool participants statements signed and affirmed in accordance with § 4.22(h) on a monthly basis within 45 days of the month-end; *Provided*, that the statements otherwise meet the conditions of paragraphs (b)(3)(i) and (ii) of this section, and that the commodity pool operator notifies its pool participants of this alternate distribution schedule in the exempt pool's offering memorandum distributed prior to the initial investment, or upon its adoption of this reporting schedule, for then existing pool participants.

* * * * *

(5) *Recordkeeping relief.* Exemption from the specific requirements of § 4.23; *Provided*, That the commodity pool operator must maintain the offering memoranda and reports referred to in

paragraphs (b)(3) and (4) of this section, and all other books and records prepared in connection with its activities as the pool operator of the exempt pool (including, without limitation, records relating to the qualifications of qualified eligible persons and substantiating any performance representations). Books and records that are not maintained at the pool operator's main business office shall be maintained by one or more of the following: the pool's administrator, distributor, or custodian, or a bank or registered broker or dealer acting in a similar capacity with respect to the pool. Such books and records must be made available to any representative of the Commission, the National Futures Association and the United States Department of Justice in accordance with the provisions of § 1.31 of this chapter.

* * * * *

■ 7. In § 4.14, revise paragraph (a)(8)(i)(C)(2) to read as follows:

§ 4.14 Exemption from registration as a commodity trading advisor.

* * * * *

- (a) * * *
- (8) * * *
- (i) * * *
- (C) * * *

(2) With the exception of the pool's operator, advisor, and their principals, solely "Non-United States persons," as that term is defined in § 4.7(a)(4), will contribute funds or other capital to, and will own beneficial interests in, the pool; *Provided*, That units of participation in the pool held by persons who do not qualify as Non-United States persons or otherwise qualified eligible persons represent in the aggregate less than 10 percent of the beneficial interest of the pool;

* * * * *

■ 8. In § 4.21, revise paragraph (a)(2) to read as follows:

§ 4.21 Required delivery of pool Disclosure Document.

- (a) * * *

(2) For the purpose of the Disclosure Document delivery requirement in this part, including any offering memorandum delivered pursuant to § 4.7(b)(2)(i) or § 4.12(b)(2)(i), the term "prospective pool participant" does not include a commodity pool operated by a pool operator that is the same as, or that controls, is controlled by, or is under common control with, the pool operator of the offered pool.

* * * * *

■ 9. In § 4.22:

■ a. Revise paragraph (a)(4), the introductory text of paragraph (c)(7),

paragraph (c)(8), the introductory text of paragraph (d)(1), the introductory text of paragraph (d)(2)(i), the introductory text of paragraph (f)(2), and paragraph (f)(2)(iv)(B); and

■ b. Remove paragraph (f)(2)(iv)(D).

The revisions read as follows:

§ 4.22 Reporting to pool participants.

- (a) * * *

(4) For the purpose of the Account Statement delivery requirement in this part, including any Account Statement distributed pursuant to § 4.7(b)(3) or § 4.12(b)(2)(ii), the term "participant" does not include a commodity pool operated by a pool operator that is the same as, or that controls, is controlled by, or is under common control with, the pool operator of a pool in which the commodity pool has invested.

* * * * *

- (c) * * *

(7) For a pool that has ceased operation prior to, or as of, the end of the fiscal year, the commodity pool operator may provide the following, within 90 days of the permanent cessation of trading, in lieu of the annual report that would otherwise be required by this paragraph (c) or § 4.7(b)(4):

* * * * *

(8) For the purpose of the Annual Report distribution requirement in this part, including any annual report distributed pursuant to § 4.7(b)(4) or § 4.12(b)(2)(iii), the term "participant" does not include a commodity pool operated by a pool operator that is the same as, or that controls, is controlled by, or is under common control with, the pool operator of a pool in which the commodity pool has invested; *Provided*, That the Annual Report of such investing pool contains financial statements that include such information as the Commission may specify concerning the operations of the pool in which the commodity pool has invested.

(d)(1) Subject to the provisions of paragraphs (d)(2) and (g)(2) of this section, the financial statements in the Annual Report required by this section or by § 4.7(b)(4) must be presented and computed in accordance with United States generally accepted accounting principles consistently applied and must be audited by an independent public accountant; *Provided, however*, and subject to the exception in paragraph (c)(7)(iii)(B) of this section, that the requirement that the Annual Report be audited by an independent public accountant does not apply for any fiscal year during which the only participants in the pool are one or more

of the pool operator, the pool's commodity trading advisor, any person controlling, controlled by, or under common control with the pool operator or trading advisor, and any principal of the foregoing; and *Provided further*, that the commodity pool operator obtains a written waiver from each such pool participant of their right to receive an audited Annual Report for such fiscal year, maintains such waivers in accordance with § 4.23, and makes such waivers available to the Commission or National Futures Association upon request. The requirements of § 1.16(g) of this chapter shall apply with respect to the engagement of such independent public accountants, except that any related notifications to be made may be made solely to the National Futures Association, and the certification must be in accordance with § 1.16 of this chapter, except that the following requirements of § 1.16 shall not apply:

* * * * *

(2)(i) Where a pool is organized in a jurisdiction other than the United States, the financial statements in the Annual Report required by this section or by § 4.7(b)(4) may be presented and computed in accordance with the generally accepted accounting principles, standards or practices followed in such other jurisdiction; *Provided*, That:

* * * * *

- (f) * * *

(2) In the event a commodity pool operator finds that it cannot obtain information necessary to prepare annual financial statements for a pool that it operates within the time specified in paragraph (c) of this section or § 4.7(b)(4)(i), as a result of the pool investing in another collective investment vehicle, it may claim an extension of time under the following conditions:

* * * * *

- (iv) * * *

(B) For all reports prepared under paragraph (c) of this section and for reports prepared under § 4.7(b)(4)(i) that are audited by an independent public accountant, the commodity pool operator has been informed by the independent public accountant engaged to audit the commodity pool's financial statements that specified information required to complete the pool's Annual Report is necessary in order for the accountant to render an opinion on the commodity pool's financial statements. The notice must include the name, main business address, main telephone number, and contact person of the accountant; and

* * * * *

PART 30—FOREIGN FUTURES AND FOREIGN OPTIONS TRANSACTIONS

■ 10. The authority citation for part 30 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 6, 6c, and 12a, unless otherwise noted.

■ 11. In § 30.6, revise paragraph (b)(1)(i) to read as follows:

§ 30.6 Disclosure.

* * * * *

(b) * * *

(1) * * *

(i) A commodity pool operator registered or required to be registered under this part, or exempt from registration pursuant to § 30.5, may not, directly or indirectly, engage in any of the activities described in § 30.4(c) unless the pool operator, at or before the time it engages in such activities, first provides each prospective qualified eligible person with the Risk Disclosure Statement set forth in § 4.24(b)(2) of this chapter and the statement in § 4.7(b)(2)(i) of this chapter;

* * * * *

PART 43—REAL-TIME PUBLIC REPORTING

■ 12. The authority citation for part 43 continues to read as follows:

Authority: 7 U.S.C. 2(a), 12a(5) and 24a, as amended by Pub. L. 111–203, 124 Stat. 1376 (2010).

■ 13. In § 43.6, revise paragraphs (i)(6)(i)(B) and (j)(1)(ii) to read as follows:

§ 43.6 Block trades and large notional off-facility swaps.

* * * * *

(i) * * *

(6) * * *

(i) * * *

(B) Is an investment adviser who has discretionary trading authority or directs client accounts and satisfies the criteria of § 4.7(a)(6)(i)(G) of this chapter; or

* * * * *

(j) * * *

(1) * * *

(ii) An investment adviser who has discretionary trading authority or directs client accounts and satisfies the criteria of § 4.7(a)(6)(i)(G) of this chapter, or

* * * * *

PART 75—PROPRIETARY TRADING AND CERTAIN INTEREST IN AND RELATIONSHIPS WITH COVERED FUNDS

■ 14. The authority citation for part 75 continues to read as follows:

Authority: 12 U.S.C. 1851.

■ 15. In § 75.10, revise paragraphs (b)(1)(ii)(B)(2) and (3) to read as follows:

§ 75.10 Prohibition on acquiring or retaining an ownership interest in and having certain relationships with a covered fund.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(B) * * *

(2) Substantially all participation units of the commodity pool are owned by qualified eligible persons defined under § 4.7(a)(6)(i) and (ii) of this chapter; and

(3) Participation units of the commodity pool have not been publicly offered to persons who are not qualified eligible persons defined under § 4.7(a)(6)(i) and (ii) of this chapter; or

* * * * *

Issued in Washington, DC, on September 18, 2024, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

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

Appendices to Commodity Pool Operators, Commodity Trading Advisors, and Commodity Pools Operated: Updating the ‘Qualified Eligible Person’ Definition; Adding Minimum Disclosure Requirements for Pools and Trading Programs; Permitting Monthly Account Statements for Funds of Funds; Technical Amendments—Commission Voting Summary and Commissioners’ Statements

Appendix 1—Commission Voting Summary

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

Appendix 2—Supporting Statement of Commissioner Summer K. Mersinger

Today, the Commission¹ achieved balance in adopting the amendments to Regulation 4.7 and for that reason I can support this final rule. I would like to thank the staff in the Market Participants Division for their hard work on this rulemaking effort and for their consideration of my suggestions and comments throughout this process.

But the balance achieved in this final rule was sorely missing in the original amendment proposal, as well as in recent

¹ This statement will refer to the Commodity Futures Trading Commission as the “Commission”, “CFTC”, or “Agency.” All web pages cited herein were last visited on September 11, 2024.

drafts of this final rule presented to the Commission. As I identified in my prior dissent, the proposed amendment to Regulation 4.7 was flawed in applying a new minimum disclosure regime on sophisticated investors who had always been exempt from such disclosures.²

This flawed proposal led to a unanimous comment file, without a single commenter supporting the Commission’s new minimum disclosure regime. The proposal was a textbook example of overregulation. Thankfully, the Commission avoided the temptation to overregulate under this rule, dropping the minimum disclosure regime from the final rule adopted today.

I am pleased that I can support this final rule. However, we should always remember that we do not regulate in a vacuum. We must work with market participants to carefully calibrate all rulemaking efforts. Additionally, we must harmonize our regulations, not only with the interests of our market participants, but with other regulators, including self-regulatory organizations.

While I am relieved that the final rule reflects a balanced approach and aims to achieve the overarching goal without overregulation, I remain concerned about the adopting release’s mention of possible future efforts to expand Regulation 4.7 after this amendment.³ I urge the Commission to avoid such future expansions, unless the Commission finds concrete evidence establishing a need for modifications and only after robust discussions with industry.

Additionally, I must caution the Commission from making the same mistake on other pending rulemaking proposals where feedback from commenters reflects a similar imbalance in the Agency’s approach. We must seek balance and compromise in our regulations, not only because we are legally obligated to do so, but also because it is the right thing to do.

Appendix 3—Statement of Commissioner Caroline D. Pham

I am pleased that the Commission is taking additional time to understand how to best protect market participants and to consider the various disclosure proposals submitted by the public in connection with the amendments to Regulation 4.7. As a market regulator with material impact on the risk management of the savings of millions of Americans, it is imperative that the Commission takes its time when considering new requirements to ensure that we get it right.

This is especially the case when the unintended consequences of our rules could create new obstacles to market participation that draw a distinction between the “have-a-lot’s” and the “have-not-enough’s”. Ultimately, using regulation to pick winners and losers that increases the wealth gap not

² Dissenting Statement of Commissioner Summer K. Mersinger On Proposal to Narrow Historical Exemptions for Qualified Eligible Persons in Rule 4.7, Oct. 2, 2023, available at: <https://www.cftc.gov/PressRoom/SpeechesTestimony/mersingerstatement100223>.

³ See Final Rule, Section II. B. 3.

only betrays the American public's expectation of Washington to create and maintain fair markets, but it also undermines financial inclusion. The government must keep the people's trust that we will help every American achieve economic mobility for them and their families—not construct artificial barriers to the American Dream.

For those reasons, I applaud the Commission taking the time for careful consideration of the public comments and further study including data. I thank Chairman Behnam and the Market Participants Division for working with me on this important rulemaking.

[FR Doc. 2024–21682 Filed 9–25–24; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 583

Publication of Global Magnitsky Sanctions Regulations Web General License 8.

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general license.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing one general license (GL) issued pursuant to the Global Magnitsky Sanctions Regulations: GL 8, which was previously made available on OFAC's website.

DATES: GL 8 was issued on September 12, 2024. 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 September 12, 2024, OFAC issued GL 8 to authorize certain transactions otherwise prohibited by the Global Magnitsky Sanctions Regulations (GMSR), 31 CFR part 583. GL 8 was made available on OFAC's website (<https://ofac.treasury.gov>) when it was issued. The text of GL 8 is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Global Magnitsky Sanctions Regulations

31 CFR part 583

GENERAL LICENSE NO. 8

Authorizing Transactions Involving Certain Entities Owned by Ly Yong Phat or L.Y.P. Group Co., LTD

(a) Except as provided in paragraph (b) of this general license, all transactions prohibited by the Global Magnitsky Sanctions Regulations, 31 CFR part 583 (GMSR), involving any entity that is blocked solely due to a property interest of Ly Yong Phat (Ly) or L.Y.P. Group Co., LTD (L.Y.P. Group) or any entity in which Ly or L.Y.P. Group owns, directly or indirectly, a 50 percent or greater interest, are authorized, provided that such entity is not identified on the Office of Foreign Assets Control's List of Specially Designated Nationals and Blocked Persons.

(b) This general license does not authorize any transactions otherwise prohibited by the GMSR, including transactions involving any person blocked pursuant to the GMSR other than the blocked persons described in paragraph (a) of this general license, unless separately authorized.

Lisa M. Palluconi, *Acting Director, Office of Foreign Assets Control*

Dated: September 12, 2024.

Lisa M. Palluconi, *Acting Director, Office of Foreign Assets Control.*

[FR Doc. 2024–21925 Filed 9–25–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2024–0376]

RIN 1625–AA08

Special Local Regulation; San Jacinto River, Houston, TX

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending its regulations for annual marine events in the Sector Houston-Galveston area of responsibility. This rulemaking establishes a special local regulation to provide for the safety of life on certain waters of the San Jacinto River, in

Houston, TX and will be enforced annually during a high-speed boat race on the first or second Saturday in March. This regulation prohibits non-registered participants from being within the specified zones unless authorized by the Captain of the Port Houston-Galveston or designated representative.

DATES: This rule is effective October 28, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0376 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Lieutenant Junior Grade Jack Brunswick, Sector Houston-Galveston Waterways Management Division, U.S. Coast Guard; telephone 713–398–5823, email houstonwww@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Houston-Galveston
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

On April 28, 2024, an organization notified the Coast Guard that it will be conducting an annual high-speed boat race from 8 a.m. to 6 p.m. on the first or second Saturday in March in the navigable waters of San Jacinto River, Houston, TX. The Captain of the Port Houston-Galveston (COTP) has determined that potential hazards associated with the power boat race will be a safety concern for anyone within the Pre-Stage Zone, Approach Zone, Course Run Zone, and Shut-Down Zone before, during, and after the scheduled event. In response, on June 24, 2024, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulation; San Jacinto River, Houston, TX (89 FR 52410). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this boat race. During the comment period that ended July 28, 2024, we received one comment.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The COTP has determined that potential hazards associated with the power boat race in San Jacinto River, Houston, TX, will be a safety concern for all non-participants within the Pre-Stage Zone, Approach Zone, Course Run Zone, and Shut-Down Zone before, during, and after the scheduled event. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within these areas during the power boat race. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received one comment on our NPRM published June 24, 2024. The comment stated concerns that are unrelated to the regulation and outside the scope of Coast Guard authority. There is one change in the regulatory text of this rule from the proposed rule. We updated the item number for this recurring event, from 8 to 9, in § 100.801, table 3.

The COTP is establishing a special local regulation that will be enforced annually on the first or second Saturday in March. Annual notice of the exact dates and times of the effective period with respect to the event, the geographical area, and additional details concerning the nature of the event and the number of participants and type(s) of vessels involved will be published in local notices to mariners. The special local regulation will encompass five different zones to include the Pre-Stage Zone, Approach Zone, Course Run Zone, Shut-Down Zone, and the Spectator Zone as described below:

Pre-Stage Zone: This is the pre-staging area for participating vessels to line up. It will include all waters within 150 ft of 29°53′29.0148″ N, 095°06′39.4416″ W.

Approach Zone: 200 ft distance required for participating vessels to obtain the minimum 40 mph requirement for course entry. This will be a straight line to begin at approximately 29°53′27.3″ N, 95°06′42.6″ W and end at approximately 29°53′27.6″ N, 95°06′40.0″ W.

Course Run Zone: 600 ft distance where participating vessels will conduct their high-speed run. This will be a straight line to begin at approximately 29°53′27.6″ N, 95°06′40.0″ W and end at approximately 29°53′30.0″ N, 95°06′34.7″ W.

Shut-Down Zone: 900 ft distance where participating vessels will be

allowed to slow their speeds back to an idle. This will be a straight line to begin at approximately 29°53′30.0″ N, 95°06′34.7″ W and end at approximately 29°53′34.3″ N, 95°06′24.1″ W.

Spectator Zone: All vessels that will be viewing the event will be required to stay within a designated area. The sponsor is responsible for monitoring the spectator zone and ensuring that all vessels within the area are anchored and remain in the area during all ongoing high-speed runs. The following coordinates are the approximate location of the Spectator Zone: 29°53′29.4″ N, 95°06′39.8″ W, thence to 29°53′28.5″ N, 95°06′39.6″ W, thence to 29°53′29.7″ N, 95°06′36.9″ W, thence to 29°53′30.4″ N, 95°06′37.2″ W.

All non-participants will be prohibited from entering the established zones without obtaining permission from the COTP, designated Coast Guard Patrol Commander, or designated representative.

The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Houston-Galveston in the enforcement of the regulated areas.

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

This regulatory action determination is based on the size, location, duration, and time of day of this special local regulation. Vessel traffic will be able to safely transit around the regulated areas, which will impact a small, designated area of the San Jacinto River, for a short duration, when vessel traffic is normally low. The Coast Guard will issue a Broadcast Notice to Mariners about the

zone via VHF-FM marine channel 16, and the rule will allow vessels to seek permission to enter the regulated areas.

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 received no comments from the Small Business Administration on this rulemaking. 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 regulated area 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 affects 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 does 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. If you believe this rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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 does not result in such an expenditure, we do discuss the potential 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 made a preliminary determination 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 marine event and special local regulation typically lasting 10 hours that will prohibit non-participants from entering specified regulated areas. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

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 100

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 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

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

■ 2. In § 100.801, in table 3 under paragraph (j), amend by adding item 9 in numerical order to read as follows:

§ 100.801 Annual Marine Events in the Eighth Coast Guard District.

* * * * *

(j) * * *

TABLE 3 OF § 100.801—SECTOR HOUSTON-GALVESTON ANNUAL AND RECURRING MARINE EVENTS

Date	Event/sponsor	Houston-Galveston location	Regulated area
* * *	* * *	* * *	* * *
9. First or Second Saturday of March.	Winter Nationals Boat Race.	San Jacinto River, Houston, TX.	San Jacinto River within 150 feet of the following area: 29°53'29.0148" N, 095°06'39.4416" W; the Approach Zone comprised of a straight line to begin at approximately 29°53'27.3" N, 95°06'42.6" W and end at approximately 29°53'27.6" N, 95°06'40.0" W; the Course Run Zone comprised of a straight line to begin at approximately 29°53'27.6" N, 95°06'40.0" W and end at approximately 29°53'30.0" N, 95°06'34.7" W; the Shut-Down Zone comprised of a straight line to begin at approximately 29°53'30.0" N, 95°06'34.7" W and end at approximately 29°53'34.3" N, 95°06'24.1" W; and the Spectator Zone located within the following coordinates; 29°53'29.4" N, 95°06'39.8" W, thence to 29°53'28.5" N, 95°06'39.6" W, thence to 29°53'29.7" N, 95°06'36.9" W, thence to 29°53'30.4" N, 95°06'37.2" W.

* * * * *

Dated: September 16, 2024.

Keith M. Donohue,

Captain, U.S. Coast Guard, Captain of the Port Sector Houston-Galveston.

[FR Doc. 2024–22015 Filed 9–25–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117**

[Docket No. USCG–2024–0018]

RIN 1625–AA09

Drawbridge Operation Regulation; Milwaukee, Menomonee, and Kinnikinnic Rivers, and South Menomonee and Burnham Canals**AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is temporarily modifying the operating schedule that governs the Cherry Street Bridge, mile 2.29, over the Milwaukee River. The Wisconsin Department of Transportation and the City of Milwaukee have requested this temporary deviation to allow contractors to complete an extensive rehabilitation of the bridge.

DATES: This temporary final rule is effective from September 26, 2024 through 11:59 p.m. on April 1, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>. Type the docket number USCG–2024–0018 in the “SEARCH” box and click “SEARCH”. In the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, email Lee.D.Soule@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 FR Federal Register
 IGLD85 International Great Lakes Datum of 1985
 LWD Low Water Datum based on IGLD85
 OMB Office of Management and Budget
 NPRM Notice of Proposed Rulemaking
 § Section
 U.S.C. United States Code

II. Background Information and Regulatory History

On April 8, 2024, the Coast Guard published a notice of proposed rulemaking (NPRM), with a request for comments, entitled, “Drawbridge Operation Regulation; Milwaukee,

Menomonee, and Kinnikinnic Rivers, and South Menomonee and Burnham Canals” in the **Federal Register** (89 FR 24396). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this temporary rule. During the sixty-day comment period that ended on June 7, 2024, we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed due to the construction project to rehabilitate the bridge that is beginning immediately.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 499. The Cherry Street Bridge, mile 2.29, over the Milwaukee River, is a double leaf bascule bridge that provides a horizontal clearance of 80-feet and a vertical clearance of 14-feet in the closed position and an unlimited clearance in the open position based on LWD and is governed by 33 CFR 117.1093.

The bridge needs extensive rehabilitation work, which will affect the ability of large vessels to pass for an extended amount of time.

This portion of the Milwaukee River is primarily transited by small unpowered vessels and occasionally by larger power-driven vessels.

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

The Coast Guard provided a sixty-day comment period, and no comments were received. The Cherry Street Bridge requires extensive electrical rehabilitation, including installation of a new submarine cable under the river bottom that will prevent the bridge from opening during installation. This type of work is typically completed during the winter months when vessel traffic is at its lowest. However, Milwaukee is hosting a national convention of nationwide significance in July 2024, and construction can not start until the convention concludes.

The vessels that normally transit the river are less than 40-feet wide but are over 14-feet in height. To accommodate their passage, one leaf of the bridge would remain open, except from November 1 through April 1, when both leaves would be secured and unable to open for any vessels.

The local DOT and City Offices provided a public information meeting in June 2023 and the proceedings can be viewed by visiting the City of Milwaukee Department of Public Works web page, available at <https://city.milwaukee.gov/dpw>. The U.S. Army Corps of Engineers will approve the installment of the submarine cable.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the continuing ability of vessels to transit the bridge through the one open leaf during the summer and that the closure of both leaves will occur during a period when ice historically prevents vessel navigation.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V.A above, this rule

will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Government

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

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

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

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

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

- 2. Amend § 117.1093 by adding paragraph (a) (6) to read as follows:

§ 117.1093 Milwaukee, Menomonee, and Kinnikinnic Rivers and South Menomonee and Burnham Canals.

(a) * * *

(6) The draw of the Cherry Street Bridge, mile 2.29, over the Milwaukee River, will, from July 22, 2024, through October 31, 2024, secure one bridge leaf in the down position and operate the

other bridge leaf normally for the passage of vessels. From November 1, 2024, through April 1, 2025, both leaves will be secured in the down position and the bridge will not open for the passage of vessels.

* * * * *

Jonathan Hickey,

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

[FR Doc. 2024–21971 Filed 9–25–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0822]

RIN 1625–AA00

Safety Zone; Commencement Bay, Washington

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of Commencement Bay, Washington. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with a marine event involving a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Sector Puget Sound.

DATES: This rule is effective from 8 p.m. through 10 p.m. on September 28, 2024.

ADDRESSES: Documents mentioned in this preamble are available in the docket at <https://www.regulations.gov>, type USCG–2024–0822 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Anthony Pinto, Waterways Management Division, U.S. Coast Guard Sector Puget Sound, telephone 206–217–6051, email SectorPugetSoundWWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Puget Sound
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 under authority in 5 U.S.C. 553(b)(B). This statutory 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.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because prompt action is required to respond to potential hazards associated with fireworks display in Commencement Bay. It is impracticable to publish an NPRM because we must establish this safety zone by September 28, 2024.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because prompt action is needed to mitigate the safety risks posed by the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The COTP has determined that potential safety hazards associated with the fireworks display necessitate the establishment of the safety zone to protect personnel, vessels, and the marine environment in the navigable waters of Commencement Bay, Washington immediately before, during, and after the fireworks display takes place.

IV. Discussion of the Rule

This rule establishes a safety zone from 8 p.m. through 10 p.m. on September 28, 2024, covering all navigable waters within a 450-yard radius of the position 47°18'7.06" N, 122°28'35.74" W in Commencement Bay, Washington. The duration of the safety zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person may enter the safety zone without obtaining permission from the COTP 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. The regulated area is limited in scope, consists of a portion of the navigable waters within Commencement Bay, Washington, affecting only a small area for a limited duration, a maximum of 2 hours. Vessel traffic will be able to safely transit around the safety zone, and vessels may seek permission from the COTP or a designated representative to transit the zone if necessary.

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, subsection 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 affects your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the

person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only 2 hours that will prohibit entry within a 450-yard radius of the barge at position 47°18'7.06" N, 122°28'35.74" W being used by the fireworks display company. 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.T13–0822 to read as follows:

§ 165.T13–0822 Safety Zone, Commencement Bay, Washington.

(a) *Location.* The following area is a safety zone: All waters within a 450-yard radius of 47°18'7.06" N, 122°28'35.74" W in Commencement Bay, Washington.

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

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by on VHF Ch 13 or Ch 16, or Coast Guard Sector Puget Sound Joint Harbor Operations Center (JHOC) via telephone at (206) 217–6002. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This rule will be enforced from 8 p.m. until 10 p.m. on September 28, 2024.

Dated: September 20, 2024.

Mark A. McDonnell,

Captain, U.S. Coast Guard, Captain of the Port Sector Puget Sound.

[FR Doc. 2024–22016 Filed 9–25–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024– 0857]

RIN 1625–AA00

Safety Zone; Lake Washington, Washington

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of Lake Washington, Washington to protect personnel, vessels, and the marine environment from potential hazards posed by low-flying aircraft during the First World Flight Centennial Celebration. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Puget Sound.

DATES: This rule is effective from 1 p.m. through 5 p.m. on September 28, 2024.

ADDRESSES: Documents mentioned in this preamble are available in the docket

at <https://www.regulations.gov>, type USCG–2024–0857 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Anthony Pinto, Waterways Management Division, U.S. Coast Guard Sector Puget Sound; telephone 206–217–6051; email SectorPugetSoundWWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Puget Sound
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 under the authority in 5 U.S.C. 553(b)(B). This statutory 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.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because prompt action is required to ensure public safety during the First World Flight Centennial Celebration over Lake Washington. It is impracticable to publish an NPRM because we must establish this safety zone by September 28, 2024.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because prompt action is needed to mitigate the safety risks posed by the airshow.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Puget Sound (COTP) has determined that potential safety hazards associated with the airshow presents an increased risk to the safety of life to make this safety zone necessary to protect personnel, vessels, and the marine environment in the navigable waters of Lake Washington, Washington immediately before, during, and after the airshow takes place.

IV. Discussion of the Rule

This rule establishes a safety zone from 1 p.m. through 5 p.m. on September 28, 2024, covering all navigable waters within Lake Washington, in the vicinity of Sand Point, starting at position 47°42'08" N, 122°15'55" W thence eastward to 47°42'26" N, 122°15'11" W thence southward to 47°40'51" N, 122°13'34" W thence westward to 47°40'32" N, 122°14'18" W. The duration of the safety zone is intended to protect personnel, vessels, and the marine environment in these navigable waters before, during, and after the airshow. No vessel or person may enter the safety zone without obtaining permission from the COTP 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. The regulated area is limited in scope, consists of a portion of the navigable waters within Lake Washington, Washington, affecting the area for a limited duration for a maximum of 4 hours. Although persons and vessels not engaged in the actual marine event will not be able to enter, transit through, anchor in, or remain within the safety zone without authorization from the COTP or a designated representative, vessel traffic will be able to safely transit around the safety zone and the rule will allow vessels to seek permission to transit the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The

term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V, subsection 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 affects your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only 4 hours that will prohibit entry within Lake Washington, Washington, in the vicinity of Sand Point, starting at position 47°42'08" N, 122°15'55" W thence eastward to 47°42'26" N, 122°15'11" W thence southward to 47°40'51" N, 122°13'34" W thence westward to 47°40'32" N, 122°14'18" W being used for the airshow. 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 protestors. 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.T13–0857 to read as follows:

§ 165.T13–0857 Safety Zone; Lake Washington, Washington.

(a) *Location.* The following area is a safety zone: all navigable waters within Lake Washington, Washington, in the vicinity of Sand Point, starting at position 47°42′08″ N, 122°15′55″ W thence eastward to 47°42′26″ N, 122°15′11″ W thence southward to 47°40′51″ N, 122°13′34″ W thence westward to 47°40′32″ N, 122°14′18″ W.

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

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by on VHF Ch 13 or Ch 16, or Coast Guard Sector Puget Sound Joint Harbor Operations Center (JHOC) via telephone at (206) 217–6002. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This rule will be enforced from 1 p.m. until 5 p.m. on September 28, 2024.

Dated: September 20, 2024.

Mark A. McDonnell,
Captain, U.S. Coast Guard, Captain of the Port Sector Puget Sound.

[FR Doc. 2024–22017 Filed 9–25–24; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 9

[PS Docket No. 18–64; FCC 24–4; FRS 245866]

Location-Based Routing for Wireless 911 Calls

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of compliance date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved information collections associated with certain rules adopted in the Location-Based Routing for Wireless 911 Calls Report and Order. The Commission also announces that compliance with the rules is now required. The Commission also removes and amends a paragraph advising that compliance was not required until OMB approval was obtained. This document is consistent with the 2024 Report and Order and rules, which state the Commission will publish a document in the **Federal Register** announcing a compliance date for the rule sections and revise the rules accordingly.

DATES:

Effective date: This rule is effective September 26, 2024.

Compliance date: Compliance with 47 CFR 9.10(s)(4) and (5), added in the final rule published March 13, 2024, at 89 FR 18488, and effective May 13, 2024, is required as of September 26, 2024.

FOR FURTHER INFORMATION CONTACT: For further information, please contact Rachel Wehr, Attorney Advisor, Policy and Licensing Division, Public Safety and Homeland Security Bureau at (202) 418–1138 or rachel.wehr@fcc.gov. For additional information concerning the Paperwork Reduction Act information collection requirements, contact Nicole Ongele at (202) 418–2991 or nicole.ongele@fcc.gov.

SUPPLEMENTARY INFORMATION: This document announces that OMB has approved the information collection requirements in 47 CFR 9.10(s)(4) and (5).

The Commission publishes this document as an announcement of the compliance date of 47 CFR 9.10(s)(4) and (5). If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Nicole Ongele, Federal Communications Commission, 45 L Street NE, Washington, DC 20554, regarding OMB Control Number 3060–1329. Please include the relevant OMB Control Number in your correspondence. The Commission will also accept your comments via the internet if you send them to PRA@fcc.gov.

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 and Governmental Affairs Bureau at (202) 418–0530 (voice).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received OMB approval on September 10, 2024, for the location-based routing information collection requirements contained in the Commission's rules at 47 CFR 9.10(s)(4) and (5).

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number.

The foregoing notification is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1329.

OMB Approval Date: September 10, 2024.

OMB Expiration Date: September 30, 2027.

Title: Location-Based Routing for Wireless 911 Calls.

Form Number: N/A.

Type of Review: New information collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 59 respondents; 59 responses.

Estimated Time per Response: 40 hours.

Frequency of Response: One-time and on occasion reporting requirement.

Obligation to Respond: Mandatory. Statutory authority for this collection is contained in sections 1, 2, 4(i), 4(j), 4(o), 251(e), 303(b), 303(g), 303(r), 316, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(j), 154(o), 251(e), 303(b), 303(g), 303(r), 316, 403, and section 4 of the Wireless Communications and Public Safety Act of 1999, Pub. L. 106–81, sections 101 and 201 of the New and Emerging Technologies 911 Improvement Act of 2008, Pub. L. 110–283, and section 106 of the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, as amended 47 U.S.C. 615a, 615a–1, 615b, 615c.

Total Annual Burden: 2,360 hours.

Total Annual Cost: No Cost.

Needs and Uses: Technical limitations of legacy Enhanced 911 (E911) routing can result in a Commercial Mobile Radio Service (CMRS) provider routing a wireless 911 call to a Public Safety Answering Point (PSAP) other than the one designated by the relevant state or local 911 authority to receive calls from the actual location of the caller. To improve emergency response times, the Commission adopted rules and procedures to require CMRS providers to implement location-based routing (LBR) for wireless 911 voice calls and real-time text (RTT) communications to 911 nationwide. With location-based routing as implemented under the Commission's rules, CMRS providers will use precise location information to route wireless 911 voice calls and RTT communications to 911 to the appropriate PSAP. To facilitate the implementation of location-based routing for wireless 911 voice calls and RTT communications to 911, and to monitor compliance, promote transparency, and ensure accountability, the Commission adopted certain information collection requirements.

Certification and reporting. The Commission will use the information collected pursuant to § 9.10(s)(4) that is submitted by the CMRS providers in their compliance certifications and reports to assess and monitor the implementation of LBR for wireless 911 voice calls and RTT communications to 911 call centers nationwide. Also, the Commission will use the data generated by the information collections to analyze the effectiveness of the LBR implementation at the benchmark dates set forth in the rules. In addition, it is imperative that CMRS providers ensure the privacy and security of location-based routing information.

Section 9.10(s)(4) requires that within 60 days after each benchmark specified in paragraphs (s)(1)(i) and (ii) and (s)(2) of § 9.10 of the rules, CMRS providers must comply with the following certification and reporting requirements.

Under § 9.10(s)(4)(i)(A), CMRS providers must certify that they are in compliance with the requirements specified in paragraphs (s)(1)(i) and (ii) and (s)(2) of this section applicable to them.

Under § 9.10(s)(4)(i)(B), CMRS providers must identify specific network architecture, systems, and procedures used to comply with paragraphs (s)(1)(i) and (ii) and (s)(2) of this section, including the extent to which the CMRS provider validates location information for routing purposes and the validation practices used in connection with this information.

Under § 9.10(s)(4)(i)(C), CMRS providers must certify that neither they nor any third party they rely on to obtain location information or associated data used for compliance with paragraph (s)(1)(i) or (ii) or (s)(2) of this section will use such location information or associated data for any non-911 purpose, except with prior express consent or as otherwise required by law. The certification must state that the CMRS provider and any third parties it relies on to obtain location information or associated data used for compliance with paragraph (s)(1)(i) or (ii) or (s)(2) of this section have implemented measures sufficient to safeguard the privacy and security of such location information or associated data.

Under § 9.10(s)(4)(ii)(A), CMRS providers must collect and report aggregate data on the routing technologies used for all live wireless 911 voice calls in the locations specified for live 911 call location data in paragraph (i)(3)(ii) of this section for a thirty-day period which begins on the compliance date(s) specified in paragraphs (s)(1)(i) and (ii) of this section. CMRS providers must retain live wireless 911 voice call data gathered pursuant to this section for a period of 2 years. CMRS providers must collect and report the following data, expressed as both a number and percentage of the total number of live wireless 911 voice calls for which data is collected pursuant to this section.

Under § 9.10(s)(4)(ii)(A)(1), CMRS providers must collect and report the live wireless 911 voice calls routed with location-based routing using location information that meets the timeliness and accuracy thresholds defined in paragraphs (s)(3)(i)(A) and (B) of this

section, expressed as both a number and percentage of the total number of live wireless 911 voice calls for which data is collected pursuant to this section.

Under § 9.10(s)(4)(ii)(A)(2), CMRS providers must collect and report the live wireless 911 voice calls routed with location-based routing using location information that does not meet the timeliness or accuracy thresholds defined in paragraphs (s)(3)(i)(A) and (B) of this section, expressed as both a number and percentage of the total number of live wireless 911 voice calls for which data is collected pursuant to this section.

Under § 9.10(s)(4)(ii)(A)(3), CMRS providers must collect and report the live wireless 911 voice calls routed using tower-based routing, expressed as both a number and percentage of the total number of live wireless 911 voice calls for which data is collected pursuant to this section.

Modification of deadlines by agreement. To monitor compliance dates agreed to between CMRS providers and PSAPs that are different from the compliance dates established by the new rules, § 9.10(s)(5) establishes notification requirements for CMRS providers. Nothing in this section of the rules shall prevent PSAPs and CMRS providers from establishing, by mutual consent, deadlines different from those established for CMRS provider compliance in paragraphs (s)(1)(i) and (ii) and (s)(2) of this section. The CMRS provider must notify the Commission of the dates and terms of the alternate time frame within 30 days of the parties' agreement or by June 11, 2024, whichever is later. The CMRS provider must subsequently notify the Commission of the actual date by which it comes into compliance with the location-based routing requirements in paragraph (s)(1)(i) or (ii) or (s)(2) of § 9.10 within 30 days of that date or by June 11, 2024, whichever is later. The CMRS providers must file any such notifications pursuant to paragraph (s)(5) in PS Docket No. 18–64.

List of Subjects in 47 CFR Part 9

Communications common carriers, Communications equipment, Radio.

Federal Communications Commission.

Marlene Dortch,
Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 9 as follows:

PART 9—911 REQUIREMENTS

- 1. The authority citation for part 9 continues to read as follows:

Authority: 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, and Section 902 of Title IX, Division FF, Pub. L. 116–260, 134 Stat. 1182, unless otherwise noted.

§ 9.10 [Amended]

- 2. Amend § 9.10 by removing paragraph (s)(6).

[FR Doc. 2024–21955 Filed 9–25–24; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 679**

[Docket No. 240227–0061; RTID 0648–XE217]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Greater Than or Equal to 50 Feet Length Overall Using Hook-and-Line Gear in the Central Regulatory Area of the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels greater than or equal to 50 feet (15.2 meters (m)) length overall using hook-and-line (HAL) gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2024 total

allowable catch (TAC) apportioned to catcher vessels greater than or equal to 50 feet (15.2 m) length overall using HAL gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), September 23, 2024, through 2400 hours, A.l.t., December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Abby Jahn, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR parts 600 and 679.

The 2024 Pacific cod TAC apportioned to catcher vessels greater than or equal to 50 feet (15.2 m) length overall using HAL gear in the Central Regulatory Area of the GOA is 1,015 metric tons (mt) as established by the final 2024 and 2025 harvest specifications for groundfish in the GOA (89 FR 15484, March 4, 2024).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the 2024 Pacific cod TAC apportioned to catcher vessels greater than or equal to 50 feet (15.2 m) length overall using HAL gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,015 mt is setting aside the remaining 0 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached.

Consequently, NMFS is prohibiting directed fishing for catcher vessels greater than or equal to 50 feet (15.2 m) length overall using HAL gear in the Central Regulatory Area of the GOA.

While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay the closure of Pacific cod by catcher vessels greater than or equal to 50 feet (15.2 m) length overall using HAL gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 20, 2024.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

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

Dated: September 23, 2024.

Karen H. Abrams,

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

[FR Doc. 2024–22112 Filed 9–23–24; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 89, No. 187

Thursday, September 26, 2024

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

FEDERAL ELECTION COMMISSION

11 CFR Part 112

[NOTICE 2024–23]

Artificial Intelligence in Campaign Ads

AGENCY: Federal Election Commission.

ACTION: Notification of disposition of Petition for Rulemaking.

SUMMARY: The Commission announces its disposition of a Petition for Rulemaking filed on July 13, 2023. The Petition asks the Commission to revise existing rules on the fraudulent misrepresentation of campaign authority to make clear that the related statutory prohibition applies to deliberately deceptive campaign ads using artificial intelligence (“AI”). For the reasons described below, the Commission is not initiating a rulemaking at this time.

DATES: September 26, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Robert M. Knop, Assistant General Counsel, or Ms. Jennifer Waldman, Attorney, 1050 First Street NE, Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Federal Election Campaign Act of 1971, as amended (the “Act”) prohibits fraudulent misrepresentation in two specific ways.¹ First, the Act prohibits a candidate, his or her employee or agent, or an organization under the candidate’s control, from purporting to speak, write, or act for another candidate or political party on a matter that is damaging to the other candidate or party.² Second, the Act prohibits any person from falsely representing that they are speaking, writing, or acting on behalf of a federal candidate or a political party for the

purpose of soliciting contributions.³ The Commission’s regulation implementing 52 U.S.C. 30124 essentially mirrors the statutory text.⁴

On July 13, 2023, Public Citizen submitted a Petition for Rulemaking (“Petition”) to the Commission, asking it to undertake a rulemaking “to clarify that the law against ‘fraudulent misrepresentation’ (52 U.S.C. 30124) applies to deliberately deceptive AI-produced content in campaign communications.”⁵ The Petition requested that the Commission initiate a rulemaking for the purpose of amending 11 CFR 110.16(a), requesting that the FEC promulgate a rule providing that “if candidates or their agents fraudulently misrepresent other candidates or political parties through deliberately false AI-generated content in campaign ads or other communications—absent clear and conspicuous disclosure in the communication itself that the content is generated by artificial intelligence and does not represent real events—then the restrictions and penalties of the law and the Code of Regulations are applicable.”⁶

On August 16, 2023, the Commission published a Notice of Availability seeking public comment on the Petition.⁷ It received more than 2,000 comments in response, including from Members of Congress, political party committees, advocacy groups across the ideological spectrum, and individual citizens. Commenters held a range of views about the desirability of opening the rulemaking requested by Petitioner.

Whether or not to open a rulemaking in response to a petition is vested within the Commission’s discretion.⁸ Petitioner asks the Commission to apply an interpretation of 52 U.S.C. 30124 specifically for “AI-produced content in campaign communications.”⁹ The statute, however, is technology neutral and applies on its face to all means of

accomplishing the specified fraud, including AI-assisted media.

Accordingly, the Commission has decided not to initiate a rulemaking at this time and will instead proceed with any application of 52 U.S.C. 30124 to specific technologies on a case-by-case basis.

Copies of the comments and the Petition for Rulemaking are available on the Commission’s website, <http://www.fec.gov/fosers/> (REG 2023–02 Artificial Intelligence in Campaign Ads (2023)) and at the Commission’s Public Records Office, 1050 First Street NE, Washington, DC 20463, Monday through Friday between the hours of 9 a.m. and 5 p.m.

Dated: September 20, 2024.

On behalf of the Commission,

Sean J. Cooksey,

Chairman, Federal Election Commission.

[FR Doc. 2024–21979 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1475; Project Identifier MCAI–2024–00062–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed rule; withdrawal.

SUMMARY: The FAA is withdrawing a notice of proposed rulemaking (NPRM) that proposed to adopt a new airworthiness directive (AD) that would have applied to all Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, –232, and –271N airplanes. The NPRM was prompted by a determination that a damage-tolerance and fatigue reassessment of nose landing gear (NLG) repairs is necessary for certain parts fitted on airplanes approved for operation in the Commonwealth of Independent States (CIS). The NPRM would have required

¹ 52 U.S.C. 30124.

² 52 U.S.C. 30124(a). *See also* Disclaimers, Fraudulent Solicitation, Civil Penalties, and Personal Use of Campaign Funds, 67 FR 76962, 76968 (Dec. 13, 2002). The Commission has explained that “on a matter that is damaging” means “actions or spoken or written communications that are intended to suppress votes for the candidate or party who has been fraudulently misrepresented.” *Id.* at 76968–69.

³ 52 U.S.C. 30124(b).

⁴ *See* 11 CFR 110.16.

⁵ Petition at 1.

⁶ Petition at 5.

⁷ *See* Notice of Availability, 88 FR 55606 (Aug. 16, 2023).

⁸ 11 CFR 200.5 (“The Commission’s decision on the petition for rulemaking may include, but will not be limited to, the following considerations—(a) The Commission’s statutory authority; (b) Policy considerations; (c) The desirability of proceeding on a case-by-case basis; (d) The necessity or desirability of a statutory revision; (e) Available agency resources”).

⁹ Petition at 1.

repair and replacement of all affected parts, and would have limited installation of affected parts, as specified in a European Union Aviation Safety Agency (EASA) AD. Since issuance of the NPRM, the FAA has determined that the applicability as specified in the NPRM was incorrect; the FAA is issuing new rulemaking that corrects the applicability. Accordingly, the NPRM is withdrawn.

DATES: As of September 26, 2024, the proposed rule, which was published in the **Federal Register** on May 24, 2024 (89 FR 45800), is withdrawn.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA-2024-1475; 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 AD action, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 206-231-3667; email *Timothy.P.Dowling@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued an NPRM that proposed to amend 14 CFR part 39 by adding an AD for all Airbus SAS Model A319-111, -112, -113, -114, -115, -131, -132, and -133 airplanes; Model A320-211, -212, -214, -216, -231, -232, and -233 airplanes; and Model A321-111, -112, -131, -211, -212, -213, -231, -232, and -271N airplanes. The NPRM was published in the **Federal Register** on May 24, 2024 (89 FR 45800). The NPRM was prompted by a determination that a damage-tolerance and fatigue reassessment of NLG repairs is necessary for certain parts fitted on airplanes approved for operation in the CIS. The NPRM proposed to require repair and replacement of all affected parts, and to limit the installation of affected parts, as specified in an EASA AD.

The proposed actions were intended to address NLG repairs for certain parts fitted on airplanes approved for operation in the CIS, and to prevent damage or failure of the affected parts and the NLG, and possible damage to the airplane and injury to occupants.

Actions Since the NPRM Was Issued

Since issuance of the NPRM, the FAA has learned of errors in the applicability. Paragraph (c)(3) of the NPRM included some airplanes that were not intended to be included, and it omitted airplanes that should have been included. In light of this error, the FAA is issuing further rulemaking (Docket No. FAA-2024-2314) to correct the applicability.

Withdrawal of the NPRM constitutes only such action and does not preclude the FAA from further rulemaking on this issue, nor does it commit the FAA to any course of action in the future.

Comments

The Air Line Pilots Association, International (ALPA) supported the NPRM. American Airlines advised the FAA of errors in the applicability specified in the NPRM.

Explanation of Applicability Errors

The following errors were included in the NPRM:

- Paragraph (c)(1) of the proposed AD incorrectly omitted Model A319-151N and -153N airplanes.
- Paragraph (c)(2) of the proposed AD incorrectly omitted Model A320-251N, -252N, -253N, -271N, -272N, and -273N airplanes.
- Paragraph (c)(3) of the proposed AD incorrectly included A321-111, -112, and -131 airplanes, and omitted Model A321-211, -212, -213, -231, -232, -251N, -251NX, -252N, -252NX, -253N, -253NX, -271N, -271NX, -272N, and -272NX airplanes.

FAA's Conclusions

Upon further consideration, the FAA has determined that the NPRM does not adequately address the identified unsafe condition. Accordingly, the NPRM is withdrawn.

Regulatory Findings

Since this action only withdraws an NPRM, it is neither a proposed nor a final rule. This action therefore is not covered under Executive Order 12866, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).

List of Subjects in 14 CFR Part 39

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

The Withdrawal

Accordingly, the notice of proposed rulemaking (Docket No. FAA-2024-1475), which was published in the **Federal Register** on May 24, 2024 (89 FR 45800), is withdrawn.

Issued on September 19, 2024.

Peter A. White,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2024-21812 Filed 9-25-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2024-2144; Project Identifier AD-2024-00424-T]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022-15-06, which applies to all The Boeing Company Model 777-200, -200LR, -300, -300ER, and 777F series airplanes. AD 2022-15-06 requires disconnecting certain connectors and capping and stowing the wires that had been attached to the affected transorb modules. Since the FAA issued AD 2022-15-06, the agency has determined additional connectors are affected. Also, a replacement has been developed to address the unsafe condition, which would terminate the existing actions. This proposed AD would continue to require the actions specified in AD 2022-15-06 and would require those actions for additional connectors. This proposed AD would also require determining if affected transorb modules are installed, replacing or testing affected transorb modules, and applicable on-condition actions. 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 proposed AD by November 12, 2024.

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

- **Federal eRulemaking Portal:** Go to *regulations.gov*. Follow the instructions for submitting comments.

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

- **Mail:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room

W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2144; 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, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For the material identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com*.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–2144.

FOR FURTHER INFORMATION CONTACT: Raja Vengadasalam, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3859; email: *raja.vengadasalam@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 the **ADDRESSES** section. Include “Docket No. FAA–2024–2144; Project Identifier AD–2024–00424–T” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Raja Vengadasalam, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3859; email: *raja.vengadasalam@faa.gov*. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2022–15–06, Amendment 39–22126 (87 FR 47334, August 3, 2022) (AD 2022–15–06), for all The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes. AD 2022–15–06 was prompted by high electrical resistance within the gust suppression sensor (GSS) transorb modules due to corrosion on the transorb threads. AD 2022–15–06 requires disconnecting certain connectors and capping and stowing the wires that had been attached to the affected transorb modules. The FAA issued AD 2022–15–06 to address high electrical resistance in both transorb modules, which can result in two actuator control electronics (ACEs) being exposed to damaging lightning transient voltages in excess of the qualification levels, potentially inducing erroneous or oscillatory outputs to flight control surfaces. The unsafe condition, if not addressed, could result in loss of control of the airplane.

Actions Since AD 2022–15–06 Was Issued

Since the FAA issued AD 2022–15–06, a replacement mitigating action has been developed to address the unsafe condition, which would terminate the existing actions. The preamble to AD 2022–15–06 explains that the FAA considers the requirements “interim

action” and may consider further rulemaking. The FAA has now determined that further rulemaking is indeed necessary, and the replacement specified in this proposed AD follows from that determination.

In addition, Boeing and several operators notified the FAA that certain bundles/connectors were not identified in AD 2022–15–06. Boeing noted that there are connector designation variances between earlier and later Model 777 airplanes and that bundle/connector W7314/D02099P is on the right-hand side of certain line number airplanes. Boeing stated it sent a Boeing multi-operator message to operators to reduce confusion and recommended bundle/connector W7314/D02099P be identified as an affected bundle/connector. American Airlines, Qatar Airways, and United Airlines also noted that bundle/connector W7314/D02099P is not identified in AD 2022–15–06. United Airlines, All Nippon Airways, and Kilita Air, LLC, noted that bundle/connector W6313/D02098P is not identified in AD 2022–15–06 but it is identified as a bundle/connector for certain airplanes.

The FAA has determined the additional connectors are affected by the unsafe condition. Therefore, this proposed AD would require that operators disconnect the connectors and cap and stow the wires to bundles/connectors W6313/D02098P and W7314/D02099P until the proposed replacement is done as specified in paragraph (h) of this proposed AD.

FAA’s Determination

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.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023. This material specifies procedures for replacing affected transorb modules with new or serviceable transorb modules or testing affected transorb modules and accomplishing applicable on-condition actions. The on-condition actions include part marking any module that meets certain specifications or replacing any modules that do not meet the specifications.

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

Proposed AD Requirements in This NPRM

This proposed AD would retain all requirements of AD 2022–15–06 and would require those actions for additional connectors. This proposed AD would also require determining if affected transorb modules are installed, replacing or testing affected transorb modules, and applicable on-condition actions. This proposed AD would also prohibit the installation of affected parts.

For information on the procedures and compliance times, see Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023, at

regulations.gov under Docket No. FAA–2024–2144.

Differences Between This Proposed AD and the Referenced Material

The effectivity of Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023, is limited to Model 777–200, –200LR, –300, –300ER, and 777F series airplanes, having certain line numbers. However, the applicability of this proposed AD includes all Model 777–200, –200LR, –300, –300ER, and 777F series airplanes. Because the affected parts are rotatable parts, the FAA has determined that these parts could later be installed

on airplanes that were initially delivered with acceptable parts, thereby subjecting those airplanes to the unsafe condition. The FAA has confirmed with Boeing that the Accomplishment Instructions in Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023, are applicable to the expanded group of airplanes.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 312 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
Disconnecting connectors, capping and stowing wires (retained actions from AD 2022–15–06).	3 work-hours × \$85 per hour = \$255	\$0	\$255	\$79,560.
Disconnecting additional connectors, capping and stowing wires (new proposed action).	3 work-hours × \$85 per hour = \$255	\$0	\$255	\$79,560.
Determining if affected transorb modules are installed, and replacing or testing affected modules (new proposed action).	Up to 3 work-hours × \$85 per hour = \$255.	Up to \$3,668	Up to \$3,923	Up to \$1,223,976.

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on

the results of the proposed testing. The agency has no way of determining the

number of aircraft that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Part marking or replacing affected modules	Up to 3 work-hours × \$85 per hour = \$255	Up to \$3,668	Up to \$3,923.

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:

■ a. Removing Airworthiness Directive (AD) 2022–15–06, Amendment 39–22126 (87 FR 47334, August 3, 2022), and

■ b. Adding the following new AD:

The Boeing Company: Docket No. FAA–2024–2144; Project Identifier AD–2024–00424–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 12, 2024.

(b) Affected ADs

This AD replaces AD 2022–15–06, Amendment 39–22126 (87 FR 47334, August 3, 2022) (AD 2022–15–06).

(c) Applicability

This AD applies to all The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Unsafe Condition

This AD was prompted by high electrical resistance within the gust suppression sensor (GSS) transorb modules due to corrosion on the transorb threads and insufficient engagement of the anti-rotation teeth. The FAA is issuing this AD to address high electrical resistance in both transorb modules, which can result in two actuator control electronics (ACEs) being exposed to damaging lightning transient voltages in excess of the qualification levels, potentially inducing erroneous or oscillatory outputs to flight control surfaces. The unsafe condition, if not addressed, could result in loss of control of the airplane.

(f) Compliance

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

(g) Retained Requirement To Disconnect, Cap, and Stow Transorb Module Connectors, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2022–15–06, with no changes. At the later of the times specified in paragraphs (g)(1) and (2) of this AD: Disconnect the connectors and cap and stow the wires to bundles/connectors W7314/D02006P and W7579/D02005P from the transorb module part numbers CLPT–12SP–06, –07, and –67.

Note 1 to the introductory text of paragraph (g): Guidance on locating wire bundles/connectors W7314/D02006P and

W7579/D02005P can be found in Section 05–55–43 of the Boeing 777 aircraft maintenance manual.

Note 2 to the introductory text of paragraph (g): Guidance on capping and stowing the wires once they are disconnected can be found in Section 20–10–11 of the Boeing Standard Wiring Practices Manual.

(1) Before the accumulation of 75,000 total flight hours or 23,000 total flight cycles, whichever occurs first.

(2) Within 3 months after August 18, 2022 (the effective date of AD 2022–15–06).

(h) New Requirement To Disconnect, Cap, and Stow Certain Other Transorb Module Connectors

At the later of the times specified in paragraphs (h)(1) and (2) of this AD: Disconnect the connectors and cap and stow the wires to bundles/connectors W6313/D02098P and W7314/D02099P from the transorb module part numbers CLPT–12SP–06, –07, and –67.

Note 3 to the introductory text of paragraph (h): Guidance on locating wire bundles/connectors W6313/D02098P and W7314/D02099P can be found in Section 05–55–43 of the Boeing 777 aircraft maintenance manual.

Note 4 to the introductory text of paragraph (h): Guidance on capping and stowing the wires once they are disconnected can be found in Section 20–10–11 of the Boeing Standard Wiring Practices Manual.

(1) Before the accumulation of 75,000 total flight hours or 23,000 total flight cycles, whichever occurs first.

(2) Within 3 months after the effective date of this AD.

(i) New Required Actions

(1) For airplanes with original airworthiness certificate or original export certificate of airworthiness issued on or before the effective date of this AD: At the later of the times specified in paragraph (i)(1)(i) or (ii) of this AD, do an inspection to determine if any airplane has a transorb module with part number CLPT–12SP–06, –07, or –67 installed. A review of airplane maintenance records is acceptable in lieu of the inspection if the part numbers can be conclusively determined from that review.

(i) Within 24 months after the effective date of this AD.

(ii) Within 24 months after the date of issuance of the original standard certificate of airworthiness or the original export certificate of airworthiness.

(2) If, during any inspection or records review required by paragraph (i)(1) of this AD, any transorb module with part number CLPT–12SP–06, –07, or –67 is found: Except as specified by paragraph (j) of this AD, at the applicable times specified in the “Compliance” paragraph of Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023. Doing the replacement required by this paragraph terminates the requirements of paragraphs (g) and (h) of this AD.

Note 5 to paragraph (i)(2): Guidance for accomplishing the actions required by paragraph (i)(2) of this AD can be found in Boeing Alert Service Bulletin 777–27A0125, dated February 3, 2023, which is referred to in Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023.

(j) Exception to Requirements Bulletin Specifications

Where the Compliance Time column of the table in the “Compliance” paragraph of Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023, refers to the original issue date of Requirements Bulletin 777–27A0125 RB, this AD requires using the effective date of this AD.

(k) Parts Installation Prohibition

As of the effective date of this AD, no person may install a transorb module, part numbers CLPT–12SP–06, CLPT–12SP–07, and CLPT–12SP–67, on any airplane.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (m)(1) of this AD. Information may be emailed to: AMOC@faa.gov.

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

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

(4) AMOCs approved for AD 2022–15–06 are approved as AMOCs for the corresponding provisions of paragraph (g) of this AD.

(m) Related Information

(1) For more information about this AD, contact Raja Vengadasalam, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3859; email: raja.vengadasalam@faa.gov.

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (n)(3) of this AD.

(n) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023.

(ii) [Reserved]

(3) For the material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website myboeingfleet.com.

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

(5) You may view this material 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 September 18, 2024.

Peter A. White,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2024–21689 Filed 9–25–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2257; Airspace Docket No. 23–ASO–53]

RIN 2120–AA66

Establishment of Class E Airspace; Brevard, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface for Transylvania Community Hospital, Brevard, NC, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures serving the heliport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at this heliport.

DATES: Comments must be received on or before November 12, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2257 and Airspace Docket No. 23–ASO–53 using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the

online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

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

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

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

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

FOR FURTHER INFORMATION CONTACT:

Robert Scott Stuart, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone: (404) 305–5926.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish Class E airspace extending upward from 700 feet above the surface at Transylvania Community Hospital, Brevard, NC, to support standard

instrument approach procedures for IFR operations at this heliport.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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 www.dot.gov/privacy.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA's web page at www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during regular business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

This action proposes to amend 14 CFR part 71 to establish Class E airspace extending upward from 700 feet above the surface within a 6-mile radius of Transylvania Community Hospital, Brevard, NC, providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for IFR operations at the heliport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures,” prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

- 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

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

* * * * *

ASO NC E5 Brevard, NC [New]

Transylvania Community Hospital, NC
(Lat. 35°15′24″ N, long. 82°42′39″ W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Transylvania Community Hospital Heliport.

* * * * *

Issued in College Park, Georgia, on July 31, 2024.

Andreea C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2024–21935 Filed 9–25–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2062; Airspace Docket No. 24–ASO–27]

RIN 2120–AA66

Establishment of Class D Airspace and Amendment of Class E Airspace; Auburn, AL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class D airspace and amend Class E airspace extending upward from 700 feet above the surface for Auburn University Regional Airport, Auburn, AL, as a new air traffic control tower will service the airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before November 12, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2062 and Airspace Docket No. 24–ASO–27 using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

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

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

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

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

FOR FURTHER INFORMATION CONTACT:

Robert Scott Stuart, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone: (404) 305–5926.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish Class D airspace and amend Class E airspace for Auburn University Regional Airport, Auburn, AL.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal considering the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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 www.dot.gov/privacy.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA's web page at www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during regular business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Incorporation by Reference

Class D and Class E airspace designations are published in paragraphs 5000 and 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will subsequently be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

This action proposes to amend 14 CFR part 71 to establish Class D airspace for Auburn University Regional Airport, Auburn, AL, as a new air traffic control tower will service the airport. Also, an airspace evaluation results in a proposal to decrease the size of the existing Class E airspace extending upward from 700 feet above the surface within a 6.9-mile by removing the extension of 1.6-miles each side of the 237° bearing from the airport, extending from the 6.9-mile radius to 11 miles southwest of the airport.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a "significant regulatory action" under Executive

Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 5000 Class D Airspace.
* * * * *

ASO AL D Auburn, AL [New]

Auburn University Regional Airport, AL
(Lat. 32°36'54" N, long. 85°26'02" W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.4-mile radius of Auburn University Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

Paragraph 6005 Class E Surface Airspace.
* * * * *

ASO AL E5 Auburn, AL [AMENDED]

Auburn University Regional Airport, AL
(Lat. 32°36'54" N, long. 85°26'02" W)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of Auburn University Regional Airport.

* * * * *

Issued in College Park, Georgia, on
September 20, 2024.

Andreese C. Davis,

*Manager, Airspace & Procedures Team South,
Eastern Service Center, Air Traffic
Organization.*

[FR Doc. 2024-22006 Filed 9-25-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2024-2222; Airspace
Docket No. 24-ASW-16]

RIN 2120-AA66

**Establishment of Class E Airspace;
Victoria, TX**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: This action proposes to establish Class E airspace at Victoria, TX. The FAA is proposing this action to support new instrument procedures at this airport.

DATES: Comments must be received on or before November 12, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA-2024-2222 and Airspace Docket No. 24-ASW-16 using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the online instruction for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

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

* *Fax:* Fax comments to Docket Operations at (202) 493-2251.

Docket: Background documents or comments received may be read at www.regulations.gov at any time.

Follow the online instructions for accessing the docket or go to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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

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

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace extending upward from 700 feet above the surface at Citizens Medical Center, Victoria, TX, to support instrument flight rule (IFR) operations at this airport.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post 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-14FDMS), which can be reviewed at www.dot.gov/privacy.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA's web page at www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing to amend 14 CFR part 71 by:

Establishing Class E airspace extending upward from 700 feet above the surface within a 6-mile radius of Citizens Medical Center, Victoria, TX. This action is to support new instrument procedures and IFR operations at this airport.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and

effective September 15, 2024, is amended as follows:

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

* * * * *

ASW TX E5 Victoria, TX [Establish]

Citizens Medical Center, TX
(Lat 28°48'43" N, long 096°58'42" W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Citizens Medical Center.

* * * * *

Issued in Fort Worth, Texas, on September 11, 2024.

Steven Phillips,

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

[FR Doc. 2024–21892 Filed 9–25–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 730, 732, 734, 736, 740, and 744

[Docket: 240923–0249]

RIN 0694–AJ43

Proposed Amendments to End-Use and End-User Based Export Controls, Including U.S. Persons Activities Controls: Military and Intelligence End Uses and End Users; Extension of Comment Period

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On July 29, 2024, the Bureau of Industry and Security (BIS) published in the **Federal Register** the proposed rule, “Proposed Amendments to End-Use and End-User Based Export Controls, Including U.S. Persons Activities Controls: Military and Intelligence End Uses and End Users” with comments originally due September 27, 2024. This notification extends the deadline for written comments to October 15, 2024. This extension is being made to allow for commenters to have additional time to review the proposed rule and to be informed by the public outreach that BIS is conducting on the rule in preparing their comments. Extending the public comment period will not in any way undermine the rule or national security of the United States.

DATES: The comments period for the proposed rule published July 29, 2024,

at 89 FR 60985 is extended. Comments must be received by BIS no later than October 15, 2024.

ADDRESSES: Comments on this rule may be submitted to the Federal rulemaking portal (www.regulations.gov). The *regulations.gov* ID for this rule is: BIS–2024–0029. Please refer to RIN 0694–AJ43 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission. For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC.” Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. The corresponding non-confidential version of those comments must be clearly marked “PUBLIC.” The file name of the non-confidential version should begin with the character “P.” Any submissions with file names that do not begin with either a “BC” or a “P” will be assumed to be public and will be made publicly available through <https://www.regulations.gov>. Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT: For questions contact Sharron Cook, Senior Export Policy Analyst in the Regulatory Policy Division of the Bureau of Industry and Security at Sharron.cook@bis.doc.gov or Phone: (202) 482–4890. Please refer to RIN 0694–AJ43 in the subject line of emails.

SUPPLEMENTARY INFORMATION:

Background

On July 29, 2024, the Bureau of Industry and Security (BIS) published in the **Federal Register** the proposed rule, “Proposed Amendments to End-Use and End-User Based Export Controls, Including U.S. Persons Activities Controls: Military and Intelligence End Uses and End Users” (RIN 0694–AJ43)

(89 FR 60985), which proposed changes to existing restrictions under the Export Administration Regulations (15 CFR parts 730 through 744) on military and intelligence end uses and end users and related U.S. persons activities controls, as well as the proposed addition of a military-support end-user control. On that same day, the Department of State published a complementary proposed rule entitled “International Traffic in Arms Regulations: Revisions to Definition and Controls Related to Defense Services” (89 FR 60980) proposing a revision to the definition of defense service at 22 CFR 120.32 of the International Traffic in Arms Regulations (22 CFR parts 120 through 130) and additions to the United States Munitions List at 22 CFR 121.1. In response to requests from the regulated community, the Department of Commerce is extending the comment period for this rule (RIN 0694-AJ43) by 15 days.

* * * * *

Thea D. Rozman Kendler,
Assistant Secretary for Export
Administration.

[FR Doc. 2024–22146 Filed 9–24–24; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 736, 744, and 774

[Docket No. 240923–0250]

RIN 0694–AI35

Export Administration Regulations: Crime Controls and Expansion/Update of U.S. Persons Controls; Extension of Comment Period

AGENCY: Bureau of Industry and
Security, Department of Commerce.

ACTION: Proposed rule; extension of
comment period.

SUMMARY: On July 29, 2024, the Bureau of Industry and Security (BIS) published in the **Federal Register** a proposed rule, “Export Administration Regulations: Crime Controls and Expansion/Update of U.S. Persons Controls” with comments originally due September 27, 2024. This notification extends the deadline for written comments to October 15, 2024. This extension is being made to allow for commenters to have additional time to review the proposed rule and to benefit from the significant amount of public outreach that BIS is conducting on the rule in preparing their comments. Extending the public comment period will not in

any way undermine the rule or national security of the United States.

DATES: The comments period for the proposed rule published July 29, 2024, at 89 FR 60998 is extended. Comments must be received by BIS no later than October 15, 2024.

ADDRESSES: Comments on this rule may be submitted to the Federal rulemaking portal (www.regulations.gov). The www.regulations.gov ID for the rule entitled “Export Administration Regulations: Crime Controls and Expansion/Update of U.S. Persons Controls” is BIS–2023–0006. Please refer to RIN 0694–AI35 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission. For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC.” Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. The corresponding non-confidential version of those comments must be clearly marked “PUBLIC.” The file name of the non-confidential version should begin with the character “P.” Any submissions with file names that do not begin with either a “BC” or a “P” will be assumed to be public and will be made publicly available through <https://www.regulations.gov>. Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT: For questions specific to the human rights or foreign-security end-user provisions set forth in the rule entitled, “Export Administration Regulations: Crime Controls and Expansion/Update of U.S. Persons Controls” contact Anthony Christino, Director Human Rights and Embargoes Division, Anthony.Christino@bis.doc.gov, Phone: (202) 482–3241. For general questions, contact Hillary Hess, Director

Regulatory Policy Division, rp22@bis.doc.gov. Include, “Human Rights End Users” on subject line of emails. Phone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

On July 29, 2024, the Bureau of Industry and Security (BIS) published in the **Federal Register** a proposed rule entitled, “Export Administration Regulations: Crime Controls and Expansion/Update of U.S. Persons Controls” (89 FR 60998), which proposed to establish certain Foreign-Security End User (FSEU) and “U.S. persons” activities controls and Commerce Control List-based (CCL) controls. The proposed additions of the foreign-security end user control and “U.S. persons” activities controls would implement expanded authority under the Export Control Reform Act of 2018 (ECRA), as amended, to control certain “U.S. persons” activities under the EAR. BIS is proposing amendments to control “support” furnished by “U.S. persons” to identified FSEUs. In addition, BIS is proposing to add to the CCL two new unilateral item controls on facial recognition technology.

In response to requests from the regulated community, the Department of Commerce is extending the comment period for 15 days.

* * * * *

Thea D. Rozman Kendler,
Assistant Secretary for Export
Administration.

[FR Doc. 2024–22145 Filed 9–24–24; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. FDA–2023–F–2319]

PHM Brands; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notification; withdrawal of
petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 2A4832) proposing that the food additive regulations for chlorine dioxide be amended to provide for an additional method for producing the additive.

DATES: The food additive petition was withdrawn on March 4, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this 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.

FOR FURTHER INFORMATION CONTACT: Karen Hall, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–9195.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 21, 2023 (88 FR 40122), we announced that we had filed a food additive petition (FAP 2A4832), submitted by Burdock Group Consultants on behalf of PHM Brands, 730 17th Street, Denver, Colorado 80202. The petition proposed to amend the food additive regulations in § 173.300 (21 CFR 173.300 *Chlorine dioxide*) to provide for production of the additive via an electrolytic method from a brine solution containing chloride salts. PHM Brands has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: September 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21934 Filed 9–25–24; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2020–0385; FRL–12224–01–R5]

Determination of Attainment by the Attainment Date; Michigan; St. Clair 2010 Sulfur Dioxide Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to determine that the St. Clair, MI sulfur dioxide (SO₂) nonattainment area attained the 2010 1-hour primary SO₂ national ambient air quality standard (NAAQS) by the date of September 12, 2021. This determination is based on annual SO₂ emissions data, modeled data, and certified ambient air quality data from EPA’s December 7, 2021, Clean Data

Determination for St. Clair, as well as publicly available additional supporting 2020 data. This action, if finalized, will address EPA’s obligation under the Clean Air Act (CAA) to determine whether the St. Clair SO₂ nonattainment area (referred to hereafter as the St. Clair area, or simply the area) attained the 2010 SO₂ NAAQS by the September 12, 2021, attainment date.

DATES: Written comments for this proposed rule must be received on or before October 28, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2020–0385 at <https://www.regulations.gov> or via email to arra.sarah@epa.gov. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA’s docket at <https://www.regulations.gov> any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), 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. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI, PBI, or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Alexis Bender, Air and Radiation Division (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–9497, bender.alexis@epa.gov. The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

SUPPLEMENTARY INFORMATION: Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

I. Background

A. The 2010 1-Hour Primary SO₂ NAAQS

Under section 109 of the CAA, EPA has established primary and secondary NAAQS for certain pervasive air pollutants (referred to as “criteria pollutants”) and conducts periodic reviews of the NAAQS to determine whether they should be revised or whether new NAAQS should be established.

On June 22, 2010 (75 FR 35520), EPA published in the **Federal Register** a strengthened, primary 1-hour SO₂ NAAQS, establishing a new standard at a level of 75 ppb, based on the 3-year average of the annual 99th percentile of daily maximum 1-hour average concentrations of SO₂. This revised SO₂ NAAQS provided increased protection of public health and provided for revocation of the 1971 primary annual and 24-hour SO₂ standards for most areas of the country following area designations under the new NAAQS.

B. Designations and Attainment Dates for the 2010 SO₂ NAAQS

Following promulgation of a new or revised NAAQS, EPA is required to designate all areas of the country as either “attainment,” “nonattainment,” or “unclassifiable,” pursuant to CAA section 107(d)(1). On July 12, 2016 (81 FR 45039), EPA finalized its second round of initial designations under the 2010 SO₂ NAAQS. During the second round of designations, the St. Clair area of Michigan was designated as nonattainment for the 2010 SO₂ NAAQS (40 CFR 81.323) based on modeling of actual emissions for the designated area.

CAA section 191(a) directs states containing an area designated nonattainment for the 2010 SO₂ NAAQS to develop and submit a nonattainment area State Implementation Plan (SIP) to EPA within 18 months of the effective date of an area’s designation as nonattainment. The Michigan Department of Environment, Great Lakes, and Energy (EGLE) was required to submit a SIP by March 12, 2018, to bring the St. Clair area into attainment by the attainment date of September 12, 2021.

EGLE submitted a request for a Clean Data Determination (CDD) on July 24, 2020. When a nonattainment area is attaining the 2010 SO₂ NAAQS based on the most recent available data, EPA may issue a CDD suspending planning requirements. EPA issued a CDD for the St. Clair area based on monitoring and modeling data for the 2017–2019 period via a final rule published on December 7, 2021 (86 FR 69173).

C. Requirement To Determine Attainment by the Attainment Date

Section 179(c)(1) of the CAA requires EPA to determine whether a nonattainment area attained a standard by the applicable attainment date based on the area’s air quality as of the attainment date. EPA is to issue this determination within six months of the attainment date. Thus, EPA had a mandatory duty under CAA section 179(c) to determine by March 12, 2022 whether the area attained by September 12, 2021. This action proposes to determine the St. Clair area did attain the 2010 SO₂ NAAQS by the attainment date of September 12, 2021.

A determination of whether an area’s air quality meets applicable standards is generally based upon the most recent three years of complete, quality-assured data gathered at established State and local air monitoring stations in a nonattainment area and entered into EPA’s Air Quality System (AQS) database. Data from ambient air monitors operated by State and local agencies in compliance with EPA monitoring requirements must be submitted to AQS. Monitoring agencies annually certify that these data are accurate to the best of their knowledge. All data are reviewed to determine the area’s air quality status in accordance with 40 CFR part 50, appendix T (for SO₂). In general, for SO₂, EPA does not rely exclusively on monitoring data to determine whether the NAAQS is met unless it has been demonstrated that the monitors were appropriately sited to record expected maximum ambient concentrations of SO₂ in an area. As such, monitoring data can be supplemented with other relevant information, including dispersion modeling and emissions inventories, for determining attainment.

II. Proposed Determination of Attainment by the Attainment Date

A. Area Characterization

The St. Clair area is located within the lower southeastern corner of Michigan northeast of Detroit and shares a border with Ontario, Canada along the St. Clair River. The area is defined by the St. Clair River for the eastern boundary, an extension from the St. Clair River straight west to the intersection of State Highway M–29 and St. Clair River Drive, continuing west on State Highway M–29 to Church Road to Arnold Road to County Line Road for the southern boundary, County Line Road and the Macomb/St. Clair County boundary to Stoddard Road to Wales Ridge Road for the western boundary, and Alpine Road to Fitz Road to Smith Creek Road to Range Road to Huron Avenue, extending straight east from the intersection of Huron Road and River Road to the St. Clair River for the northern boundary.

The St. Clair area contains two SO₂-emitting facilities that are both coal-fired power plants. Additionally, the area contains two SO₂ monitors which reside near the facilities. The two monitors have been operating since 2016 and have had no recorded violations of the NAAQS. As these monitors were sited to operate under guidance per the “SO₂ NAAQS Designations Source-Oriented Monitoring Technical Assistance Document” (SO₂ Monitoring TAD), EPA believes that these monitors’ locations adequately represent the locations of potential maximum SO₂ impacts from the two power plants.

B. St. Clair Nonattainment Area’s Attainment of the 2010 SO₂ NAAQS

We propose to determine that the St. Clair nonattainment area attained the 2010 SO₂ NAAQS by the attainment date of September 12, 2021. EPA previously determined that the St. Clair SO₂ nonattainment area was attaining

the 2010 SO₂ NAAQS in its December 7, 2021 (86 FR 69173), CDD. EPA issued the CDD based on SO₂ monitoring and modeling data from EGLE. For this determination of attainment by the attainment date, EPA is in part relying on the approved CDD of the St. Clair area as well as additional supporting information. The data cited by the CDD demonstrated attainment for the 2017–2019 time period, with averaged SO₂ monitoring values of 54 ppb for the Belle River-Mills Monitor and 45 ppb for the St. Clair-Remer Monitor. The CDD modeled 2017–2019 emission sources for an overall maximum 99th percentile impact output of 64.4 ppb, which falls below the 2010 SO₂ NAAQS of 75 ppb.

As noted, determinations of whether areas attained the NAAQS by the attainment date are generally based on the area’s design value as of the attainment date, *i.e.*, the three most recent calendar years of data, in this case 2018–2020. Therefore, in this proposal EPA is closely examining monitoring and emissions data from 2020 to supplement the analysis already concluded in the CDD, which looked at air quality information from 2017–2019. In 2020, primary source SO₂ emissions and monitored SO₂ ambient air concentrations in the area continued to decline. The SO₂ emissions from the Belle River and St. Clair power plants decreased by an additional total of 8,996 tons per year from 2019 to 2020 (Table 1). As seen in Table 2, the 2018–2020 design values at the two air quality monitors in the area continued to show SO₂ levels below the 75 ppb level of the NAAQS and a decline in SO₂ concentration from 2017–2019. Therefore, the additional information EPA has examined for 2020, coupled with the existing CDD based on 2017–2019 monitoring and emissions data, leads the agency to conclude that the St. Clair nonattainment area attained by its attainment date.

TABLE 1—ST. CLAIR, MI NONATTAINMENT AREA ANNUAL EMISSIONS

SO ₂ emissions		Power plant	Total tons/year
Year			
2017	Belle River/St. Clair	36,918
2018	Belle River/St. Clair	41,381
2019	Belle River/St. Clair	30,751
2020	Belle River/St. Clair	21,755

TABLE 2—ST. CLAIR, MI NONATTAINMENT AREA 2010 SO₂ NAAQS STANDARD 3-YEAR DESIGN VALUES

Power plant monitors		3-Year design values (ppb)	
Site ID		2017–2019	2018–2020
26–147–0913	Belle River-Mills	45	40
26–147–0914	St. Clair-Remer	54	45

III. Proposed Action and Request for Public Comment

Based on EPA's review of all available evidence described in this notice, EPA is proposing to determine that the St. Clair nonattainment area attained the 2010 SO₂ NAAQS by the relevant attainment date of September 12, 2021.

The determination of attainment by the attainment date does not constitute a redesignation of the St. Clair, MI nonattainment area to attainment of the 2010 SO₂ NAAQS under section 107(d)(3) of the CAA. If this action is finalized, the St. Clair area will remain designated nonattainment for the 2010 SO₂ NAAQS until such time as EPA approves a redesignation request and accompanying 10-year maintenance plan, and EPA determines that the area meets the requirements of CAA section 107(d)(3) and provides for maintenance as required by CAA section 175A.

If finalized, this action will address EPA's obligation under CAA section 179(c) to determine if the St. Clair Area attained the 2010 SO₂ NAAQS by the attainment date of September 12, 2021.

EPA is soliciting public comments on this action. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

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

This action is not a “significant regulatory action” under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Order 14094 (88 FR 21879, April 11, 2023).

B. Paperwork Reduction Act (PRA)

This rule does not impose an information collection burden under the provisions of the PRA of 1995 (44 U.S.C. 3501 *et seq.*). This action does not contain any information collection activities and serves only to make a final determination that the St. Clair, Michigan nonattainment area attained the 2010 SO₂ NAAQS by the September 12, 2021, attainment date.

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 (5 U.S.C. 601 *et seq.*). The determination of attainment by attainment date action of attaining the 2010 SO₂ NAAQS will not impose any requirements on small entities or will not create any new requirements beyond what is mandated by the CAA.

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 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. The division of responsibility between the Federal Government and the States for purposes of implementing the NAAQS is established under the CAA.

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

Executive Order 13175 (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications.” This action does not have Tribal implications as specified in Executive Order 13175. This action does not apply on any Indian reservation land, any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction, or non-reservation areas of Indian country. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying 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 establish an environmental standard intended to mitigate health or safety risks.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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

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

risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.”

EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for communities with EJ concerns.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Sulfur dioxide.

Dated: September 18, 2024.

Debra Shore,

Regional Administrator, Region 5.

[FR Doc. 2024–21895 Filed 9–25–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[GN Docket No. 20–32; FCC 24–89; FRS 246488]

Petitions for Reconsideration of Action in Rulemaking Proceeding; Correction

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; correction.

SUMMARY: This document makes an editorial correction to the date in a citation that appeared in the **Federal Register** on September 17, 2024. That **Federal Register** document, which invited comment on the 5G Fund Second Further Notice of Proposed Rulemaking, incorrectly listed the date on which a summary of the Commission’s 2023 5G Fund Further Notice of Proposed Rulemaking was published in **Federal Register** as September 28, 2024. The correct date is September 28, 2023.

DATES: The corrections are effective September 26, 2024.

FOR FURTHER INFORMATION CONTACT: Valerie Barrish, Office of Economics and

Analytics, Auctions Division, (202) 418–0660, or Valerie.Barrish@fcc.gov.

SUPPLEMENTARY INFORMATION: This document makes an editorial correction in a citation that appeared in the summary of the 5G Second Further Notice of Proposed Rulemaking, published at 89 FR 76016 on September 17, 2024, which incorrectly listed incorrectly listed the date on which a summary of the Commission’s 2023 5G Fund Further Notice of Proposed Rulemaking was published in **Federal Register** as September 28, 2024, rather than September 28, 2023.

In FR Doc. 2024–20979 appearing on page 76016 in the **Federal Register** of Tuesday, September 16, 2024, the following correction is made:

1. On page 76017, in the first column, in the Synopsis in the **SUPPLEMENTARY INFORMATION**, in paragraph number 2., the date “(Sept. 28, 2024)” is corrected to read “(Sept. 28, 2023)”.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2024–21968 Filed 9–25–24; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 89, No. 187

Thursday, September 26, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency’s estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by October 28, 2024 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.

Animal Plant and Health Inspection Service

Title: APHIS National Incident Management System (NIMS) Training and Exercise Program (NTEP).

OMB Control Number: 0579–NEW.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. Under APHIS Directive 1810.2, APHIS National Incident Management System (NIMS) Training and Exercise Program, APHIS is assuming responsibility for providing the following FEMA related training to APHIS employees. Seats not filled by APHIS employees will be made available to state, local and tribal government respondents. The information collected from the respondents will include an application email and a course evaluation sheet. The course roster (affidavit) confirming attendance will be completed by the instructor.

The NIMS training consists of subjects, such as, the Introduction to the Incident Command System (ICS), ICS for Initial Response, ICS for Expanding Incidents, and advanced training to employees who require advanced knowledge of the ICS. The training will also provide an overview for Executives and Senior Officials with and introduction and overview of ICS. Additional training includes an overview of NIMS and the National Response Framework focusing especially on those who are involved in delivering and applying the response core capabilities.

Need and Use of the Information: APHIS uses the following information collection activities to support the APHIS National Incident Management System (NIMS) Training and Exercise:

Course Enrollment; (APHIS Directive 1810.2); (State; Local; Tribal)

Respondents desiring to enroll into an APHIS-offered NIMS course must submit a course enrollment request, with their name and contact email, to NIMS.Training@usda.gov. Slots are available on a first-come first-serve basis after APHIS employee requests are filled.

Course Roster; (APHIS Form 353); (Federal)

The course roster is considered an affidavit and is not reportable as an activity.

NIMS Course Evaluation (APHIS Form 354); (APHIS Directive 1810.2); (State; Local; Tribal)

At the conclusion of each course, student participants will be asked to complete a NIMS Course Evaluation Sheet to provide feedback on course effectiveness, instructor preparation, and facility provisions.

NIMS Course Evaluation (APHIS Form 354); (APHIS Directive 1810.2); (State; Local; Tribal)

At the conclusion of each course, student participants will be asked to complete a NIMS Course Evaluation Sheet to provide feedback on course effectiveness, instructor preparation, and facility provisions.

Description of Respondents: State, Local, and Tribal governments.

Number of Respondents: 300.

Frequency of Responses: Reporting: On occasion; Recordkeeping: Annual.

Total Burden Hours: 75.

Rachelle Ragland-Greene,

Departmental Information Collection Clearance Officer.

[FR Doc. 2024–22051 Filed 9–25–24; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request; Reinstatement

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and reinstatement under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency’s estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to

respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology.

Comments regarding this information collection received by October 28, 2024 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.

Rural Business-Cooperative Service

Title: Rural Micro-Entrepreneur Assistance Program.

OMB Control Number: 0570–0062.

Summary of Collection: The Rural Microentrepreneur Assistance Program (RMAP), authorized under section 6022 of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill), which amends section subtitle D of the Consolidated Farm and Rural Development Act of 2008 (CON Act) provides rural microentrepreneurs with the skills necessary to establish new rural microenterprises, to provide continuing technical and financial assistance related to the successful operation of rural microenterprises, and to assist with the cost of providing other activities and services related to the successful operation of rural microenterprise development organizations (MDOs) and rural microenterprises. The Secretary makes direct loans to MDOs (MDOs that are participating in the program are referred to as “microlenders”) for the purpose of capitalizing microloan revolving funds to provide fixed interest rate business loans of \$50,000 or less to microentrepreneurs, as defined in the 2008 Farm Bill.

Need and Use of the Information: Microlenders seeking loans and/or grants will have to submit applications that include specified information, certifications, and agreements to the Agency. This information will be used to determine applicant eligibility and to

ensure that funds are used for authorized purposes. Applications for continued participation in RMAP, during years 2 and 3, will include primarily any needed updates to the information submitted with the initial application.

Description of Respondents: Business or other for-profit; Not-for-profit Institutions; State, Local or Tribal governments.

Number of Respondents: 40.

Frequency of Responses: Reporting: Quarterly, Annually.

Total Burden Hours: 1,907.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2024–22071 Filed 9–25–24; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Forest Service

Proposed Recreation Fee Sites

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice.

SUMMARY: The National Forests in Mississippi are proposing to establish a recreation fee site and two special recreation permits. Proposed recreation fees collected at the proposed recreation fee site and for the proposed special recreation permits would be used for operation, maintenance, and improvement of the site and the specialized recreation use covered by the proposed special recreation permit. An analysis of nearby recreation fee sites and specialized recreation uses with similar amenities shows the proposed recreation fees that would be charged at the proposed recreation fee site and for the proposed special recreation permit are reasonable and typical of similar recreation fee sites and specialized recreation uses in the area.

DATES: If approved, the proposed recreation fees would be established no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: National Forests in Mississippi, Attention: Recreation Fees, 968 Highway 15 South, Laurel, MS 39443.

FOR FURTHER INFORMATION CONTACT:

Jacob Rhyne, Recreation Program Manager, 601–804–9767 or Jacob.rhyne@usda.gov.

SUPPLEMENTARY INFORMATION: The Federal Lands Recreation Enhancement Act (16 U.S.C. 6803(b)) requires the

Forest Service to publish in the **Federal Register** a six-month advance notice of establishment of recreation fee sites. In accordance with Forest Service Handbook 2309.13, chapter 30, the Forest Service will publish the proposed recreation fee sites and proposed recreation fees in local newspapers and other local publications for public comment. Most of the proposed recreation fees would be spent where they are collected to enhance the visitor experience at the proposed recreation fee sites.

A proposed expanded amenity recreation fee of \$10 per night would be charged for Big Foot Horse Camp. A proposed special recreation permit recreation fee of \$10 per person per day is proposed at the South Bethel Motorized Trail. In addition, a proposed special recreation permit recreation fee of \$5 per person per day is proposed at the Black Creek Shooing Range.

Expenditures of recreation fees collected at the proposed recreation fee site and for the proposed special recreation permits would enhance recreation opportunities, improve customer service, and address maintenance needs. Once public involvement is complete, the proposed recreation fee site, proposed special recreation permits, and proposed recreation fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation.

Dated: September 19, 2024.

Jacqueline Emanuel,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–22007 Filed 9–25–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Eldorado and Stanislaus National Forests; California; Mokelumne Amador Calaveras Forest Resilience Project

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: The Forest Service (“Forest Service”), United States Department of Agriculture is preparing an Environmental Impact Statement (EIS) for the Mokelumne Amador Calaveras (MAC) Forest Resilience Project. The MAC Forest Resilience Project is a 246,838-acres planning effort designed to address the threats wildfire and

climate change elicit to watershed resiliency at a scale and intensity that will be effective in improving our ability to protect communities, critical infrastructure, wildlife habitat and ecosystem services. Current forest conditions have placed the Project Area at an elevated risk of high-severity wildfires. The proposed action includes vegetation management treatments designed to better align current forest structure and composition with desired conditions, focusing on fuel reduction, forest thinning, prescribed fire, fuel break construction and maintenance, non-native invasive plant control and eradication, and other ecological and watershed restoration activities. The Planning, Appeals, and Litigation System identification number for the project is 65796.

DATES: Comments concerning the scope of the analysis must be received by October 28, 2024. The draft environmental impact statement is expected mid-2025 and the final environmental impact statement is expected early 2026.

ADDRESSES: Submit written comments via mail or by hand delivery to Eldorado National Forest Supervisor's Office at 100 Forni Road, Placerville, CA 95667. Comments may be submitted electronically online via the project website <https://www.fs.usda.gov/project/?project=65796>. From the project website, click on the 'Comment/Object on Project' link located on the right-hand side under the 'Get Connected' box.

FOR FURTHER INFORMATION CONTACT: Carinna Robertson, Resource Management Staff Officer via email at carinna.robertson@usda.gov, or by phone at 1-209-813-6039. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800-877-8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose of MAC Forest Resilience Project is to restore ecosystem health and resilience to wildfire, insect and disease, drought, and climate change; reduce safety hazards across public lands; reduce the spread of non-native species; maintain and support local economies, and maintain and improve aspen groves, riparian areas, streams, and meadows. The proposed actions are needed to reduce the risks of wildfire within and adjacent to USDA Forest Service managed lands, improve and maintain safe ingress/egress routes for fire

personnel, equipment, and the public, maintain and promote plant and wildlife habitat and biodiversity, and reduce the spread of non-native invasive plants.

Proposed Action

The MAC Forest Resilience Project will include a broad range of management activities to meet the purpose and need of the project. A combination of commercial and non-commercial mechanical forest thinning, other mechanical and hand fuel treatments, prescribed fire, hazard tree removal, salvage logging, invasive species treatments, and additional ecological restoration activities are proposed. Forest thinning will be implemented to reduce fuel loads, reduce stand densities, and increase forest heterogeneity across the landscape. Multiple logging systems, road maintenance, temporary road construction, and landing development will be required for product removal during forest thinning.

Shaded fuel breaks will be constructed and maintained to break up large expanses of continuous fuels, support firefighter access and safety, and provide control points for the implementation of prescribed fire.

Prescribed fire treatments will be implemented, including, but not limited to, pile burning and understory broadcast burning, to reduce fuel loads, increase understory productivity and diversity, and allow fire to perform its natural ecological role.

Hazard trees will be identified, felled, and removed to improve safety along roadways, recreation areas, trails, access routes, infrastructure, and other specific areas. Salvage of insect-, disease-, drought-, and fire-killed trees is included to efficiently eliminate accumulated fuels and to facilitate a rapid response to mortality events.

Non-native invasive plant control and eradication treatments are proposed for known infestations and for future new infestations. Manual, biological, and chemical control or targeted grazing methods will be used to eradicate infestations or to contain or control their spread.

Ecological restoration activities will include aspen grove maintenance and improvement, riparian improvements such as native plant plantings and streambank stabilization, removal of encroaching conifers and trail and road rerouting around meadows, as well as process-based stream restoration techniques and aquatic organism passage improvements.

Treatments will be implemented using a staged approach over the next 10

years. Follow-up treatments to achieve or maintain desired conditions will be implemented beyond 10 years. To determine priorities and locations for treatments, spatial modeling will be used to identify focus areas for maximizing effectiveness. The proposed action will include an extensive list of management requirements, including restrictions, constraints, and retention requirements for protection of resources and to ensure compliance with applicable laws, regulations, and policy.

Forest Plan Amendments

The proposed action will include project-specific forest plan amendments to implement the management approaches and conservation measures presented in the Conservation Strategy for the California Spotted Owl in the Sierra Nevada (USDA Forest Service 2019).

The EIS will also consider an alternative developed in compliance with the existing Forest Plans to enable a comparative assessment of the proposed action developed in compliance with the project-specific forest plan amendments and similar actions proposed under current plan direction. The Eldorado and Stanislaus Forests will each make independent decisions on the potential future adoption of any project-specific Forest Plan amendments included in the EIS.

Expected Impacts

The MAC Forest Resilience Project EIS will evaluate both the effectiveness of the proposed action and action alternative(s) at meeting the purpose and needs of the project and the potential environmental consequences of these proposed actions in comparison to the no action alternative. The EIS will focus the analysis to address significant issues identified through the public scoping process. The project is expected to significantly increase forest health and resilience by reducing the likelihood of high-severity wildfire, reducing stand densities, and increasing forest heterogeneity. Restoration to healthier, more resilient and more fire-resistant forests will reduce uncontrolled emissions and public health impacts from wildfire smoke over the long term, improve growth, life span, and carbon storage of residual trees. Surface water quality, supply, and reliability will be protected by reducing fire-induced soil erosion, benefiting local and downstream users, hydroelectric and water supply infrastructure, and special-status species.

The consequences of taking no action are high. The area would remain at an

elevated risk of high-severity wildfire that would result in forest and wildlife habitat losses and watershed degradation. The treatments proposed to create the desired conditions may cause short-term impacts to sensitive resources, including California spotted owl protected activity centers.

Responsible Officials

The Responsible Officials will be Amy Reid, Acting Forest Supervisor, Eldorado National Forest, and Jason Kuiken, Forest Supervisor, Stanislaus National Forest.

Scoping Comments and the Objection Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. In this process the Agency is requesting comments on potential alternatives and impacts, and identification of any relevant information, studies, or analyses of any kind concerning impacts affecting the quality of the human environment. There will be up to two public workshops during the scoping period.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the final EIS; therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions. Commenting during scoping and any other designated opportunity to comment provided by the Responsible Official as prescribed by the applicable regulations will also govern eligibility to object once the final EIS and draft Record of Decision has been published. Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however, they will not be used to establish eligibility for the objection process.

Objections will be accepted only from those who have previously submitted specific written comments regarding the proposed project during scoping or other designated opportunity for public comment in accordance with § 218.5(a). Issues raised in objections must be based on previously submitted timely, specific written comments regarding the proposed project unless based on new information arising after designated opportunities.

Permits, Licenses or other Authorizations Required

The Project includes actions within aquatic or riparian areas that may be subject to future permitting requirements under Section 404 of the Clean Water Act (CWA), Section 401 of the CWA, and/or Section 1600 et seq of California Fish and Game Code.

Additionally, the Project will require consultation with the United States Fish and Wildlife Service (USFWS) on listed species. Based on current and potential future funding from the state of California, compliance with the California Environmental Quality Act will be required.

Nature of Decision To Be Made

Given the purpose and need, the Responsible Officials will determine whether the proposed actions comply with all applicable laws governing Forest Service actions and with the applicable standards and guidelines found in the Forest Plans of the Eldorado National Forest and Stanislaus National Forest; whether the EIS has sufficient environmental analysis to make an informed decision; and whether the proposed action and any action alternatives meet the purpose and needs for action. With this information, the Responsible Officials must decide whether to select the proposed action and what, if any, additional actions should be required.

Substantive Provisions

The substantive provisions of 36 CFR 219.8 through 219.11 that may directly apply to the proposed project-specific forest plan amendments are 36 CFR 219.9 Diversity of Plant and Animal Communities, (a) Ecosystem plan components, (1) Ecosystem integrity (36 CFR 219 (a)(1)); 36 CFR 219.9 Diversity of Plant and Animal Communities, (a) Ecosystem plan components, (2) Ecosystem diversity, (i) key characteristics associated with the terrestrial and aquatic ecosystem types (36 CFR 219(a)(2)(I)); 36 CFR 219.9 Diversity of Plant and Animal Communities, (a) Ecosystem plan components, (2) Ecosystem diversity, (ii) rare aquatic and terrestrial plant and animal communities (36 CFR 219 (a)(2)(ii)); and 36 CFR 219.8 Sustainability, (b) Social and Economic Sustainability, (1) Social, cultural, and economic conditions relevant to the area

influenced by the plan (36 CFR 219.8(b)(1)).

Keith Lannom,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–22038 Filed 9–25–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Office of the Secretary

[Docket Number: 240918–0243]

RIN 0605–XZ001

Department of Commerce Open Government Plan

AGENCY: Office of the Secretary, Department of Commerce.

ACTION: Request for comments for the Department of Commerce Open Government Plan; reopening of comment period.

SUMMARY: On August 7, 2024, the U.S. Department of Commerce's Office of Privacy and Open Government issued a request for public comments (RFC) on improvements to the presentation of the Department's eighth Open Government Plan. That request sought public input on how to improve upon the organization, scope, form, and format of the Department's seventh Open Government Plan document, how to enhance readability and reach a broader audience, and how best to convey in the document how the Department's eighth Open Government Plan incorporates themes from the fifth U.S. Open Government National Action Plan that was issued on December 28, 2022. The comment period for the Open Government Plan closed on September 6, 2024. Unfortunately, the RFC was not available for public comments via the Federal eRulemaking Portal at <https://www.regulations.gov/>. Accordingly, the Department hereby reopens the comment period for an additional 60 days.

DATES: The comment period for the notice published August 7, 2024, at 89 FR 64405, is reopened. Comments on this notice must be submitted on or before November 25, 2024.

ADDRESSES: You may submit comments via the Federal eRulemaking Portal at <https://www.regulations.gov/>. Follow the instructions for submitting comments. All public comments received are subject to the Freedom of Information Act and will be posted in their entirety at <https://www.regulations.gov/>, including any personal and business confidential

information provided. Only include information you would like to be made public.

Instructions: Response to this RFC is voluntary. Responses should include the name of the person(s) or organization(s) filing the response. Responses containing references, studies, research, and other empirical data that are not widely published should include copies of or electronic links to the referenced materials. Please do not submit copyrighted material. OPOG will not consider responses containing profanity, vulgarity, threats, or other inappropriate language or content. Any information obtained from this RFC is intended to be used by the Government on a non-attribution basis. The Department of Commerce will not respond to individual submissions.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to open@doc.gov with "Open Government Plan RFC" in the subject line, or by mail to Office of Privacy and Open Government, U.S. Department of Commerce, Attn: Jennifer Goode, Ph.D., Deputy Director for Open Government and Departmental Privacy Act Officer, 1401 Constitution Ave. NW, Mail Stop 61013, Washington, DC 20230, (202) 482-1190.

SUPPLEMENTARY INFORMATION: In accordance with OMB Memorandum M-09-12, President's Memorandum on Transparency and Open Government—Interagency Collaboration, OMB Memorandum M-10-06, Open Government Directive, and OMB Memorandum M-16-16, 2016 Agency Open Government Plans, the Department continues to develop, publish, and update its Open Government Plan every two years. The Plan describes how the Department continuously strives to improve transparency and integrate public participation and collaboration into its activities. In September 2022, the Department published the seventh version of its Open Government Plan, building on the Department's long history of innovative approaches to data dissemination and highlighting the adoption of new tools and technology to facilitate the principles of open government.

Now, as the Department develops the eighth version of its Open Government Plan, we welcome public input on how to improve upon the approach we took for the presentation of the seventh version of the Open Government Plan, including how to improve the organization, scope, form and format of the plan; enhance readability; and reach a broader audience. We also welcome

public input on how best to convey how the Department will incorporate the following themes from the fifth U.S. Open Government National Action Plan, issued on December 28, 2022:

- improving access to government data, research, and information;
 - increasing civic space within which to engage with the public;
 - transforming government service delivery;
 - countering corruption and ensuring government integrity and accountability to the public; and
 - ensuring equal justice under the law.
- Please Note:** The focus of this request for information is the presentation of the Department's Open Government Plan document. Comments or suggestions for improvements to the Department's programs or activities in furtherance of open government will not be considered in connection with this request for information.

To learn more about the Department's commitment to open government and to access the seventh or previous versions of the Department's Open Government Plan, visit www.commerce.gov/open. To learn more about the fifth U.S. Open Government National Action Plan, visit: <https://open.usa.gov/national-action-plan/5/>.

Charles R. Cutshall,

Department of Commerce, Director of Open Government, Office of Privacy and Open Government.

[FR Doc. 2024-21731 Filed 9-25-24; 8:45 am]

BILLING CODE 3510-17-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-50-2024]

Foreign-Trade Zone (FTZ) 49, Notification of Proposed Production Activity; Merck, Sharp & Dohme LLC; (Pharmaceutical Products for Research and Development); Rahway, New Jersey

Merck, Sharp & Dohme LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Rahway, New Jersey, within Subzone 49Y. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on September 18, 2024.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) and specific finished product(s) described in the submitted notification (summarized below) and

subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz. The proposed finished product and material/component would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed finished product for research and development is MK-6878 HIV drug product (duty-free).

The proposed foreign-status material/component is MK-6878 HIV active pharmaceutical ingredient (duty rate, 6.5%). The request indicates that this material/component is subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is November 5, 2024.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact Diane Finver at Diane.Finver@trade.gov.

Dated: September 23, 2024.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2024-22102 Filed 9-25-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-29-2024]

Foreign-Trade Zone (FTZ) 32; Authorization of Production Activity; J.J.C. International Distributors LLC dba Clar Company; (Galvanized Steel Products); Miami, Florida

On May 23, 2024, J.J.C. International Distributors LLC dba Clar Company submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 32, in Miami, Florida.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (89 FR 47129, May 31, 2024). On September 20, 2024, the

applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: September 20, 2024.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2024–21970 Filed 9–25–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Renewing Temporary Denial of Export Privileges; UTair Aviation JSC, Khanty-Mansiysk Airport Tyumen Region, Russia 628012

Pursuant to section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (“EAR” or “the Regulations”),¹ I hereby grant the request of the Office of Export Enforcement (“OEE”) to renew the temporary denial order (“TDO”) issued in this matter on September 23, 2023. I find that renewal of this order is necessary in the public interest to prevent an imminent violation of the Regulations and that renewal for an extended period is appropriate because UTair Aviation JSC (“UTair”) has engaged in a pattern of repeated, ongoing and/or continuous apparent violations of the EAR.

I. Procedural History

On April 7, 2022, I signed an order denying UTair's export privileges for a period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order was issued *ex parte* pursuant to Section 766.24(a) of the Regulations

and was effective upon issuance.² The temporary denial order was subsequently renewed on October 3, 2022,³ March 29, 2023,⁴ and September 23, 2023⁵ in accordance with section 766.24(d) of the Regulations.⁶

On August 27, 2024, BIS, through OEE, submitted a written request for renewal of the TDO that issued on September 23, 2023. The written request was made more than 20 days before the TDO's scheduled expiration and, given the temporary suspension of international mail service to Russia, OEE has attempted to deliver a copy of the renewal request to UTair by alternative means in accordance with sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received.

II. Renewal of the TDO

A. Legal Standard

Pursuant to section 766.24, BIS may issue an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an “imminent violation” of the Regulations, or any order, license or authorization issued thereunder. 15 CFR 766.24(b)(1) and 766.24(d). “A violation may be ‘imminent’ either in time or degree of likelihood.” 15 CFR 766.24(b)(3). BIS may show “either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.” *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge “is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent[.]” *Id.* A “lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient

reason to believe the likelihood of a violation.” *Id.*

If BIS believes that renewal of a denial order is necessary in the public interest to prevent an imminent violation, it may file a written request for renewal, with any modifications if appropriate. 15 CFR 766.24(d)(1). The written request, which must be filed no later than 20 days prior to the TDO's expiration, should set forth the basis for BIS's belief that renewal is necessary, including any additional or changed circumstances. *Id.* “In cases demonstrating a pattern of repeated, ongoing and/or continuous apparent violations, BIS may request the renewal of a temporary denial order for an additional period not exceeding one year.”⁷ *Id.*

B. The TDO and BIS's Request for Renewal

The U.S. Commerce Department, through BIS, responded to the Russian Federation's (“Russia's”) further invasion of Ukraine by implementing a sweeping series of stringent export controls that severely restrict Russia's access to technologies and other items that it needs to sustain its aggressive military capabilities. These controls primarily target Russia's defense, aerospace, and maritime sectors and are intended to cut off Russia's access to vital technological inputs, atrophy key sectors of its industrial base, and undercut Russia's strategic ambitions to exert influence on the world stage. Effective February 24, 2022, BIS imposed expansive controls on aviation-related (e.g., Commerce Control List Categories 7 and 9) items to Russia, including a license requirement for the export, reexport or transfer (in-country) to Russia of any aircraft or aircraft parts specified in Export Control Classification Number (“ECCN”) 9A991 (Section 746.8(a)(1) of the EAR).⁸ BIS will review any export or reexport license applications for such items under a policy of denial. *See* section 746.8(b). Effective March 2, 2022, BIS excluded any aircraft registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia from being eligible for license exception Aircraft, Vessels, and Spacecraft (“AVS”) (Section 740.15 of the EAR).⁹ Accordingly, any U.S.-origin

⁷ 88 FR 59791 (Aug. 30, 2023).

⁸ 87 FR 12226 (Mar. 3, 2022). Additionally, BIS published a final rule effective April 8, 2022 which imposed licensing requirements on items controlled on the Commerce Control List (“CCL”) under Categories 0–2 that are destined for Russia or Belarus. Accordingly, now all CCL items require export, reexport, and transfer (in-country) licenses if destined for or within Russia or Belarus. 87 FR 22130 (Apr. 14, 2022).

⁹ 87 FR 13048 (Mar. 8, 2022).

¹ On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (“ECRA”). While section 1766 of ECRA repeals the provisions of the Export Administration Act, 50 U.S.C. App. 2401 *et seq.* (“EAA”), (except for three sections which are inapplicable here), section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (“IEEPA”), and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders. 50 U.S.C. 4820(a)(5).

² The TDO was published in the **Federal Register** on April 12, 2022 (87 FR 21616).

³ The October 3, 2022 renewal order, which was effective upon issuance, was published in the **Federal Register** on October 7, 2022 (87 FR 60987).

⁴ The March 29, 2023 renewal order, which was effective upon issuance, was published in the **Federal Register** on April 4, 2023 (88 FR 19911).

⁵ The September 23, 2023 renewal order, which was effective upon issuance, was published in the **Federal Register** on September 28, 2023 (88 FR 66802).

⁶ Section 766.24(d) provides that BIS may seek renewal of a temporary denial order for additional 180-day renewal periods, if it believes that renewal is necessary in the public interest to prevent an imminent violation. In cases demonstrating a pattern of repeated, ongoing and/or continuous apparent violations, BIS may request the renewal of a temporary denial order for an additional period not exceeding one year.

aircraft or foreign aircraft that includes more than 25% controlled U.S.-origin content, and that is registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia, is subject to a license requirement before it can travel to Russia.

OEE's request for renewal for a period of one year is based upon the facts underlying the issuance of the initial TDO and the renewal orders subsequently issued in this matter, as well as other evidence developed during this investigation. These facts and evidence demonstrate that UTair has continued, and continues, to act in blatant disregard for U.S. export controls and the terms of previously issued TDOs. Specifically, the initial TDO, issued on April 7, 2022, was based on evidence that UTair engaged in conduct prohibited by the Regulations by operating multiple aircraft subject to the EAR and classified under ECCN 9A991.b on flights into Russia after March 2, 2022 from destinations including, but not limited to, Jeddah, Saudi Arabia, Yerevan, Armenia, and Tashkent, Uzbekistan, without the

required BIS authorization.¹⁰ Further evidence submitted by BIS indicated that UTair was continuing to operate aircraft subject to the EAR domestically on flights within Russia, potentially in violation of section 736.2(b)(10) of the Regulations.

As discussed in the October 3, 2022, March 29, 2023, and September 23, 2023 renewal orders, evidence presented by BIS indicated that, after the initial order issued, UTair continued to operate aircraft subject to the EAR and classified under ECCN 9A991.b on flights both into and out of Russia, in violation of the Regulations and the TDO itself.¹¹ Specifically, the October 3, 2022 renewal order detailed UTair's continued operation of aircraft subject to the EAR, including, but not limited to, on flights into and out of Russia from/to Yerevan, Armenia, Baku, Azerbaijan, and Tashkent, Uzbekistan.¹² Similarly, the March 29, 2023 renewal order detailed UTair's continued operation of aircraft subject to the EAR, including, but not limited to, on flights into and out of Russia from/to Yerevan, Armenia, Baku, Azerbaijan, Dushanbe, Tajikistan, and Dubai, United Arab

Emirates ("UAE").¹³ The September 23, 2023 renewal order outlined UTair's further operation of aircraft subject to the EAR including, but not limited to, on flights into and out of Russia from/to Yerevan, Armenia, Baku, Azerbaijan, Dushanbe, Tajikistan, Istanbul, Turkey, Tashkent, Uzbekistan, and Dubai, UAE.¹⁴

Since that time, UTair has continued to engage in conduct prohibited by the applicable TDO and Regulations. In its August 27, 2024 request for renewal of the TDO, BIS submitted evidence that UTair is operating aircraft subject to the EAR and classified under ECCN 9A991.b, both on flights into and within Russia, in violation of the September 23, 2023 TDO and/or the Regulations. Specifically, BIS's evidence and related investigation demonstrates that UTair has continued to operate aircraft subject to the EAR, including, but not limited to, on flights into and out of Russia from/to Khujand, Tajikistan, Istanbul, Turkey, Dubai, UAE, Baku, Azerbaijan, Samarkand, Uzbekistan, Bukhara, Uzbekistan, and Bishkek, Kyrgyzstan. Information about those flights includes, but is not limited to, the following:

Tail No.	Serial No.	Aircraft type	Departure/arrival cities	Dates
RA-73089	37552	737-8GU (B738)	Khujand, TJ/Tyumen, RU	August 11, 2024.
RA-73089	37552	737-8GU (B738)	Istanbul, TR/Grozny, RU	September 6, 2024.
RA-73089	37552	737-8GU (B738)	Dubai, AE/Grozny, RU	September 8, 2024.
RA-73087	29936	737-8AS (B738)	Samarkand, UZ/Moscow, RU	August 5, 2024.
RA-73087	29936	737-8AS (B738)	Baku, AZ/Moscow, RU	August 14, 2024.
RA-73087	29936	737-8AS (B738)	Baku, AZ/Moscow, RU	September 9, 2024.
RA-73085	32779	737-8AS (B738)	Bukhara UZ/Moscow, RU	August 3, 2024.
RA-73085	32779	737-8AS (B738)	Baku, AZ/Moscow, RU	August 13, 2024.
RA-73085	32779	737-8AS (B738)	Samarkand, UZ/St Petersburg, RU	September 10, 2024.
RA-73086	32780	737-8AS (B738)	Bishkek, KG/Surgut RU	August 11, 2024.
RA-73086	32780	737-8AS (B738)	Baku, AZ/Moscow, RU	August 12, 2024.
RA-73086	32780	737-8AS (B738)	Baku, AZ/Moscow, RU	September 10, 2024.

III. Findings

Under the applicable standard set forth in section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that UTair has acted in violation of the Regulations and the TDO; that such violations have been significant and deliberate; and that given the foregoing and the nature of the matters under investigation, there is a

likelihood of imminent violations. Moreover, I find that renewal for an extended period is appropriate because UTair has engaged in a pattern of repeated, ongoing and/or continuous apparent violations of the EAR. Therefore, renewal of the TDO for one year is necessary in the public interest to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they

should avoid dealing with UTair, in connection with export and reexport transactions involving items subject to the Regulations and in connection with any other activity subject to the Regulations.

IV. Order

It is therefore ordered:

First, UTair Aviation JSC, Khanty-Mansiysk Airport, Tyumen Region, Russia 628012, when acting for or on

¹⁰ Publicly available flight tracking information shows that on March 5, 2022, serial number (SN) 36387 flew from Jeddah, Saudi Arabia to Grozny, Russia, and on March 30, 2022, SN 28907 flew from Yerevan, Armenia to Tyumen, Russia. In addition, on March 31, 2022, SN 30437 flew from Tashkent, Uzbekistan to Moscow, Russia.

¹¹ Engaging in conduct prohibited by a denial order violates the Regulations. 15 CFR 764.2(a) and (k).

¹² Publicly available flight tracking information shows that on September 19, 2022, SN 30437 flew from Tashkent, Uzbekistan to Moscow, Russia, and SN 30435 flew from Yerevan, Armenia to Moscow, Russia. In addition, on September 21, 2022, SN 28912 flew from Baku, Azerbaijan to Moscow, Russia.

¹³ Publicly available flight tracking information shows that SN 37752 flew from Yerevan, Armenia to Moscow, Russia on March 23, 2023 and from Dubai, United Arab Emirates to Grozny, Russia on

March 28, 2023. In addition, on March 29, 2023, SN 30437 flew from Dushanbe, Tajikistan to Moscow, Russia and on March 7, 2023, SN 28912 flew from Baku, Azerbaijan to Ufa, Russia.

¹⁴ Publicly available flight tracking information shows that SN 37552 flew from Istanbul, Turkey to Grozny, Russia on September 19, 2023, SN 29936 flew from Yerevan, Armenia to Moscow, Russia on September 15, 2023. In addition, SN 32780 flew from Dushanbe, Tajikistan to Moscow, Russia on September 8, 2023.

their behalf, any successors or assigns, agents, or employees may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as “item”) exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license (except directly related to safety of flight), license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations, or engaging in any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of UTAir any item subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by UTAir of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby UTAir acquires or attempts to acquire such ownership, possession or control except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from UTAir of any item subject to the EAR that has been exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

D. Obtain from UTAir in the United States any item subject to the EAR with

knowledge or reason to know that the item will be, or is intended to be, exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by UTAir, or service any item, of whatever origin, that is owned, possessed or controlled by UTAir if such service involves the use of any item subject to the EAR that has been or will be exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to UTAir by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of sections 766.24(e) of the EAR, UTAir may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by UTAir as provided in section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to UTAir, and shall be published in the **Federal Register**.

This Order is effective immediately and shall remain in effect for one year.

Matthew S. Axelrod,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2024–21947 Filed 9–25–24; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–179]

Certain Tungsten Shot From People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation

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

DATES: Applicable September 26, 2024.

FOR FURTHER INFORMATION CONTACT:

Samuel Evans at (202) 482–2420, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On August 6, 2024, the U.S. Department of Commerce (Commerce) initiated a countervailing duty (CVD) investigation of imports of certain tungsten shot (tungsten shot) from the People's Republic of China.¹ Currently, the preliminary determination is due no later than October 10, 2024.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner² makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On September 12, 2024, the petitioner submitted a timely request that

¹ See *Certain Tungsten Shot from the People's Republic of China: Initiation of Countervailing Duty Investigation*, 89 FR 65852 (August 13, 2024).

² The petitioner is Tungsten Parts Wyoming, Inc.

Commerce postpone the preliminary CVD determination.³ The petitioner stated that it requests postponement because Commerce has not yet received questionnaire responses and requires more time to gather all necessary information.⁴

In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determination, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determination to no later than 130 days after the date on which this investigation was initiated, *i.e.*, December 16, 2024.⁵ Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination.

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

Dated: September 19, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–21972 Filed 9–25–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE311]

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a meeting of its Law Enforcement

Technical Committee (LETC), in conjunction with the Gulf States Marine Fisheries Commission's (GSMFC) Law Enforcement Committee (LEC).

DATES: The meeting will convene on Wednesday, October 16, 2024; beginning at 7:30 a.m. until 12 p.m., CDT. The Committees will be in a closed session from 7:30 a.m. until 8:15 a.m. CDT.

ADDRESSES: The meeting will be held at The Lodge at Gulf State Park, located at 21196 E Beach Boulevard, Gulf Shores, AL 36542; (251) 540–4000. Please visit the Gulf Council website (www.gulfcouncil.org) for agenda and meeting materials information.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. Max Birdsong, Social Scientist, Gulf of Mexico Fishery Management Council; max.birdsong@gulfcouncil.org, telephone: (813) 348–1630, and Mr. Steve VanderKooy, Inter-jurisdictional Fisheries (IJF) Coordinator, Gulf States Marine Fisheries Commission; svanderkooy@gsmfc.org, telephone: (228) 875–5912.

SUPPLEMENTARY INFORMATION: The following items of discussion are on the agenda, though agenda items may be addressed out of order and any changes will be noted on the Council's website when possible.

Joint Gulf Council's Law Enforcement Technical Committee and Gulf States Marine Fisheries Commission's Law Enforcement Committee Meeting Agenda

*Wednesday, October 16, 2024;
Beginning at 8:30 a.m.–12 p.m., CDT*

The joint meeting will begin in a CLOSED SESSION from 7:30 a.m.–8:15 a.m., CDT with introductions, case work discussions and any other business.

General session will begin at approximately 8:30 a.m., CDT. with introductions and adoption of agenda, and approval of minutes from the Joint LEC/LETC meeting from October 2023 and election of Joint Committee Chair and Vice Chair.

The Gulf Council LETC will hold a review and discuss the Federal Charter Vessel ID Marking Requirements and 20-Fathom Recreational Seasonal Closure for *Shallow-water Grouper*.

The GSMFC LEC will review the IJF Program Activity for *Gray (Mangrove) Snapper* Profile Status, *Black Drum* Profile and Commission Pubs.

The committee will present the State Report Highlights from Florida,

Alabama, Mississippi, Louisiana, Texas, U.S. Coast Guard (USCG, NOAA Office of Law Enforcement (OLE), and U.S. Fish and Wildlife Service (USFWS); and will discuss any Other Business items.

—Meeting Adjourns

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on www.gulfcouncil.org.

The LETC consists of principal law enforcement officers in each of the Gulf States, as well as the NOAA OLE, USFWS, the USCG, and the NOAA Office of General Counsel for Law Enforcement.

Although other non-emergency issues not on the agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in the agenda 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 Council's intent to take action to address the emergency.

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

Dated: September 23, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024–22104 Filed 9–25–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA)

National Integrated Drought Information System (NIDIS) Executive Council Meeting

AGENCY: Climate Program Office (CPO), Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: The National Integrated Drought Information System (NIDIS) Program Office will hold an organizational meeting of the NIDIS Executive Council on October 24, 2024.

DATES: The meeting will be held Thursday, October 24, 2024 from 8:30 a.m. EST to 3:30 p.m. EST. These times and the agenda topics are subject to change.

³ See Petitioner's Letter, "Request to Postpone Preliminary CVD Determination," dated September 12, 2024.

⁴ *Id.* at 2.

⁵ Postponing the preliminary determination to 130 days after initiation would place the deadline on Saturday, December 14, 2024. Commerce's practice dictates that where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. See *Notice of Clarification: Application of "Next Business Day" Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended*, 70 FR 24533 (May 10, 2005).

ADDRESSES: The meeting will be held at the Hall of the States, Room 333, 444 North Capitol St. NW, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Veva Deheza, NIDIS Executive Director, David Skaggs Research Center, Room GD102, 325 Broadway, Boulder CO 80305. Email: Veva.Deheza@noaa.gov; or visit the NIDIS website at www.drought.gov.

SUPPLEMENTARY INFORMATION: The National Integrated Drought Information System (NIDIS) was established by Public Law 109–430 on December 20, 2006, and reauthorized by Public Law 113–86 on March 6, 2014 and Public Law 115–423 on January 7, 2019, with a mandate to provide an effective drought early warning system for the United States; coordinate, and integrate as practicable, Federal research in support of a drought early warning system; and build upon existing forecasting and assessment programs and partnerships. See 15 U.S.C. 313d. The Public Law also calls for consultation with “relevant Federal, regional, State, tribal, and local government agencies, research institutions, and the private sector” in the development of NIDIS. 15 U.S.C. 313d(c). The NIDIS Executive Council provides the NIDIS Program Office with an opportunity to engage in individual consultation with senior resource officials from NIDIS’s Federal partners, as well as leaders from state and local government, academia, nongovernmental organizations, and the private sector.

Status: This meeting is in-person and will be open to public participation. Individuals interested in attending should register at <https://cpaess.ucar.edu/meetings/nidis-executive-fall-council-meeting-2024>. Please refer to this web page for the most up-to-date meeting times and agenda. Seating at the meeting will be available on a first-come, first-served basis.

Special Accommodations: This meeting is physically accessible to people with disabilities. Requests for special accommodations may be directed no later than 12:00 p.m. on October 17, 2024, to Elizabeth Ossowski, Senior Program Manager, David Skaggs Research Center, Room GD102, 325 Broadway, Boulder, CO 80305; Email: Elizabeth.Ossowski@noaa.gov.

Matters to be Considered: The meeting will include the following topics: (1) NIDIS implementation updates and 2024 priorities; (2) Executive Council member updates and

2024 priorities relevant to Drought, Climate Adaptation and Resilience, Water, Fire; (3) Building out the National Drought Early Warning System and Partnership Opportunities; and (4) Advances in Drought and Low Flow Water Prediction.

David Holst,

Chief Financial Officer/Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2024–22042 Filed 9–25–24; 8:45 am]

BILLING CODE 3510–KB–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE308]

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 87 Assessment Webinar II for Gulf of Mexico White, Pink, and Brown Shrimp.

SUMMARY: The SEDAR 87 assessment process of Gulf of Mexico white, pink, and brown shrimp will consist of a Data Workshop, and a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 87 Assessment Webinar II will be held Tuesday, October 15, 2024, from 1 p.m. to 4 p.m., Eastern Time.

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 Assessment webinar II are as follows:

Participants will review the assessment modeling work to date and provide recommendations to the analytic team.

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: September 23, 2024.

Rey Israel Marquez,

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

[FR Doc. 2024-22103 Filed 9-25-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Withdrawal of Notice of Intent (NOI) To Prepare a Draft Environmental Impact Statement for Modification of the Bayou Lafourche and Lafourche-Jump Waterway, Louisiana, Navigation Channel Project in Lafourche Parish

AGENCY: U.S. Army Corps of Engineers, Department of the Army, DoD.

ACTION: Notice of intent; withdrawal.

SUMMARY: The U.S. Army Corps of Engineers (USACE) is issuing this notice to advise Federal, State, and local governmental agencies, and the public that USACE is withdrawing the notice of intent (NOI) for the preparation of the Draft Environmental Impact Statement for Modification of the Bayou Lafourche and Lafourche-Jump Waterway, Louisiana, Navigation Channel Project in Lafourche Parish, which was published in the **Federal Register** on November 23, 2016. The Nonfederal Sponsor, the Greater Lafourche Port Commission, drafted an Environmental Impact Statement (EIS) and Feasibility Report, which was submitted to the ASA-CW. In 2020, their EIS had an addendum to adjust the controlling depth of the Bayou Lafourche Waterway Federal navigation channel at Port Fourchon, Louisiana, to an engineering, economic and environmentally feasible depth and extend the main access channel to the natural contour of the Gulf of Mexico at the optimum depth. Since then, there has been a reduction of scope which involves less impacts than was anticipated at the time of the NOI, resulting in moving to an Environmental Assessment.

DATES: The notice of intent to prepare an EIS published in the **Federal Register** on November 23, 2016 (81 FR 84562), is withdrawn as of September 26, 2024.

ADDRESSES: Department of the Army, U.S. Army Corps of Engineers, New Orleans District, 7400 Leake Avenue, New Orleans, LA 70118-3651.

FOR FURTHER INFORMATION CONTACT: Questions about the withdrawal of the Notice of Intent can be directed to Jordan Logarbo, (504) 862-1158 at Jordan.r.logarbo@usace.army.mil.

SUPPLEMENTARY INFORMATION: The reduction in scope includes the following: an adjustment of the proposed dredge depth from the previous proposed maximum dredge depth of -50 ft mean lower low water (MLLW) to a proposed elevation of -30 ft MLLW for the inland reach plus 3 ft of advanced maintenance and to -32 ft MLLW for the offshore reach plus 4 ft of advanced maintenance, and the proposed channel deepening would not require an increase in channel width. The disposal area has also been changed from a marsh creation project to nearshore disposal on the west and east sides of the jetties.

The existing maintenance project was authorized for a navigation channel 300 ft wide with an elevation of -24 ft MLLW on the inland reach for mile 3.4 to Mile 0.0 and to an elevation of -26 ft MLLW for the offshore reach from Mile 0.0 to Mile -1.3. The Port Fourchon Federal navigation channel has been maintained by USACE within the proposed action dimensions and alignment.

The Federal proposed plan includes deepening and maintenance of the Port Fourchon Federal navigation channel which was considered through a 50-year period of analysis. The proposed dredging would start at approximately Station 0+00 and end at approximately Station 330+00. Deepening would be achieved by the same dredging operation that is currently used for maintenance. The existing maintenance project was authorized by WRDA 1996 for a navigation channel 300 ft wide with an elevation of -24 ft MLLW on the inland reach for mile 3.4 to Mile 0.0 and to an elevation of -26 ft MLLW for the offshore reach from Mile 0.0 to Mile -1.3. The proposed action would dredge the Federal navigation channel to an elevation of -30 ft MLLW for the inland reach plus 3 ft of advanced maintenance and to -32 ft MLLW for the offshore reach plus 4 ft of advanced maintenance. The proposed action follows the alignment of the existing maintenance project and extends to the newly authorized limits following the natural contour of the Gulf of Mexico. Dredging would be accomplished with a hydraulic cutter-head dredge and material excavated would be transported to two (2) sites in a slurry via pipeline. The two dredge material disposal sites are located on the exterior of the existing jetties near the intersection with the existing shoreline. Discharge location would be 200 ft offshore and would extend 300-3,000 ft from the jetties in the shallow open water and be allowed to flow.

The study was authorized by section 203 of the Water Resources and Development Act (WRDA) of 1986 (Pub. L. 99-662) as modified by section 1014 of Water Resources and Reform Development Act (WRRDA) 2014. Also, by section 1126 of the Water Infrastructure Improvements of the Nation Act (Pub. L. 114-322) which is also known as WRDA of 2016, and section 1152 of WRDA 2018. Section 203, as amended via the above referenced provisions, allows non-Federal interests, such as GLPC, to undertake feasibility studies of proposed navigation projects and submit them to the (ASA-CW).

The Draft EA was made available for a 30-day public review and comment period beginning on May 17, 2024 and ending on June 15, 2024 and can be found on the study website at <https://www.mvn.usace.army.mil/About/Projects/Port-Fourchon/>.

James A. Bodron,

Program Director, Mississippi Valley Division.

[FR Doc. 2024-22030 Filed 9-25-24; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2024-SCC-0118]

Agency Information Collection Activities; Comment Request; Multi-Purpose Financial Information Statement

AGENCY: Federal Student Aid (FSA), 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 of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before November 25, 2024.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2024-SCC-0118. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the [regulations.gov](http://www.regulations.gov) site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov.

Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 4C210, Washington, DC 20202–1200.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–570–8414.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Multi-purpose Financial Information Statement.

OMB Control Number: 1845–NEW.

Type of Review: A new ICR.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 415,542.

Total Estimated Number of Annual Burden Hours: 261,791.

Abstract: This is a request for a new collection. The information collected through this new form will support both involuntary collection and voluntary

resolution of defaulted Federal student loans in the following categories: Involuntary collection where the Department of Education (ED) and guaranty agencies utilize two methods to involuntarily collect defaulted student loans: the Treasury Offset Program (TOP) and Administrative Wage Garnishment (AWG). And voluntary resolution: defaulted borrowers can resolve their loan balance by making voluntary payments or through the loan rehabilitation program authorized by the Higher Education Act of 1965, as amended, and described in regulations at 34 CFR 682.405(b)(1)(iii) and 34 CFR 685.211(f). ED will use the new form in place of the existing Loan Rehabilitation: Income and Expense Information form (OMB No. 1845–0120) and will allow schools and guaranty agencies to use the new form for the same purposes for which ED will use it. Note that guaranty agencies may continue to use the current form in lieu of the new form if they choose.

Dated: September 23, 2024.

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. 2024–22109 Filed 9–25–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Docket No. 12–156–LNG]

Golden Pass LNG Terminal LLC; Request for Extension of Commencement Deadline

AGENCY: Office of Fossil Energy and Carbon Management, Department of Energy.

ACTION: Notice of request.

SUMMARY: The Office of Fossil Energy and Carbon Management (FECM) of the Department of Energy (DOE), formerly the Office of Fossil Energy (FE), gives notice (Notice) of receipt of a request (Request) filed by Golden Pass LNG Terminal LLC (GPLNG or Golden Pass LNG) on August 28, 2024. GPLNG requests an extension of the deadline in its current authorization to export domestically produced liquefied natural gas (LNG) to non-free trade agreement countries, set forth in DOE/FE Order No. 3978, as amended, to allow GPLNG to commence commercial export operations from the proposed GPLNG Export Terminal by March 31, 2027. This modification would extend GPLNG's existing commencement

deadline by eighteen months. GPLNG filed the Request under the Natural Gas Act (NGA) and pursuant to DOE's Policy Statement on Export Commencement Deadlines in Authorizations to Export Natural Gas to Non-Free Trade Agreement Countries (Commencement Extension Policy). Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene, or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed as detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, October 28, 2024.

ADDRESSES:

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

Postal Mail, Hand Delivery, or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E–056, 1000 Independence Avenue SW, Washington, DC 20585.

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

FOR FURTHER INFORMATION CONTACT:

Jennifer Wade or Peri Ulrey, U.S.

Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–4749 or (202) 586–7893, jennifer.wade@hq.doe.gov or peri.ulrey@hq.doe.gov

Cassandra Bernstein, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Energy Delivery and Resilience, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (240) 780–1691, cassandra.bernstein@hq.doe.gov

SUPPLEMENTARY INFORMATION:

Background

On April 25, 2017, in DOE/FE Order No. 3978 (as amended),¹ DOE

¹ *Golden Pass LNG Terminal LLC*, DOE/FE Order No. 3978, Docket No. 12–156–LNG (Apr. 25, 2017), *reh'g denied*, DOE/FE Order No. 3978–A (Mar. 30, 2018), *amended by* DOE/FE Order No. 3978–B (Mar. 4, 2020) (transferring authorization from Golden Pass Products LLC to Golden Pass LNG Terminal LLC), *further amended by* DOE/FE Order No. 3978–C (Mar. 24, 2020) (extending export commencement

authorized GPLNG to export domestically produced LNG by vessel from the proposed GPLNG Export Terminal² in Sabine Pass, Texas, to any country with which the United States does not have a free trade agreement (FTA) requiring national treatment for trade in natural gas, which currently has or in the future develops the capacity to import LNG, and with which trade is not prohibited by U.S. law or policy (non-FTA countries).³ GPLNG is authorized to export this LNG in a volume equivalent to 937 billion cubic feet per year of natural gas for a term extending through December 31, 2050.⁴

GPLNG notes that the Federal Energy Regulatory Commission (FERC) initially approved its Project facilities, including the Terminal, in 2016.⁵ GPLNG has also asked FERC to extend the in-service deadline associated with the Project facilities—currently November 30, 2026.⁶

As relevant here, Order No. 3978, as amended, requires GPLNG to make its first export of LNG from the Terminal no later than September 30, 2025.⁷

Request for Extension

In its Request, GPLNG asks DOE to extend the deadline for commencement of commercial LNG export operations from the GPLNG terminal by 18 months to March 31, 2027.⁸ GPLNG states that the additional 18-month period would account “for both the delays caused by the bankruptcy filing of the lead construction contractor, Zachry

Industrial Inc. [(Zachry)], remaining uncertainties regarding the transition to a new lead contractor, possible unpredictable delays that may occur during the remaining construction activities such as potential hurricane impacts, and for commissioning and start-up activities.”⁹ GPLNG maintains that its Request is consistent with DOE’s April 2023 Policy Statement on Export Commencement Deadlines,¹⁰ and that its proposed exports remain consistent with the public interest under NGA section 3(a).¹¹

In support of its Request, GPLNG asserts that good cause exists to grant the requested conditional extension of time, and that GPLNG’s authorized exports remain in the public interest. GPLNG also states that it meets the criteria established by DOE in the Commencement Extension Policy for such requests. Specifically, GPLNG argues that “an extension of the commercial operations deadline is necessary due to extenuating circumstances outside of [its] control,”¹² and that it “has been continuously and steadily engaged in construction” of the export facilities for over five years.¹³ GPLNG represents that at the time it filed its Request, “the LNG Facility [was] approximately 80% complete, including design and engineering work, and 65% complete in terms of physical construction.”¹⁴ GPLNG executed an engineering, procurement, and construction (EPC) contract in January 2019, with Zachry as lead contractor.¹⁵ GPLNG states that Zachry was not able to complete the Project following a series of problems, and that Zachry notified GPLNG of its plan to exit the Project in April 2024, then filed for bankruptcy in May 2024.¹⁶ Although another party to the EPC contract has taken over as lead construction contractor, GPLNG is not confident that the Project can be completed by the current commencement deadline.¹⁷

Additionally, GPLNG contends not only that its proposed exports are consistent with the public interest regardless of its commencement deadline, but also that “cancelling the Project at this stage would be affirmatively contrary to the public interest.”¹⁸ GPLNG states that it has already invested billions of dollars in the Project, has over one thousand active operations contracts, and “has sold 100% of the LNG production.”¹⁹ GPLNG concludes that “the public interest is served by this request to avoid the tremendous loss of jobs, economic activity, tax revenue benefiting state, regional and local governments, and billions of dollars of sunk private investment.”²⁰

Additional details can be found in the Request, posted on the DOE website at: <https://www.energy.gov/sites/default/files/2024-08/Binder1.pdf>.

DOE Evaluation

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

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

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

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable, addressing the Request. Interested parties will be provided 30 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention. The public previously was given an opportunity to intervene in, protest, and comment on GPLNG’s non-FTA application in Docket No. 12–156–LNG.²¹ Therefore, DOE will not consider comments or protests that do not bear directly on this Request.

Any person wishing to become a party to this proceeding evaluating GPLNG’s

deadline), further amended by DOE/FE Order No. 3978–D (Dec. 10, 2020) (extending export term), further amended by DOE/FE Order No. 3978–E (Apr. 27, 2022) (increasing authorized volume), *reh’g denied*, DOE/FE Order No. 3978–F (June 24, 2022). In addition, GPLNG’s export authorization was amended by DOE/FE Order No. 4641 (Dec. 18, 2020) to include short-term export authority on a non-additive basis.

² The initial order authorized exports from the “existing Golden Pass LNG Terminal.” The facility, with later modifications—and including those currently under construction—is now known as the GPLNG Export Terminal.

³ 15 U.S.C. 717b(a).

⁴ DOE/FE Order No. 3978, as amended in DOE/FE Order No. 3978–E (Ordering Para. A).

⁵ *Golden Pass Prods. LLC & Golden Pass Pipeline LLC*, 157 FERC ¶ 61,222 (2016).

⁶ *Golden Pass LNG Terminal LLC*, Request for Extension of Commencement Deadline, Docket Nos. 12–156–LNG and 12–88–LNG, at 2 n.6 (Aug. 28, 2024) [hereinafter Request]. The “in-service deadline” refers to the date by which the Project’s facilities must be operational under FERC’s authorization, rather than the date by which commercial exports must begin under DOE’s authorization.

⁷ DOE/FE Order No. 3978–E, at 53 (Ordering Para. A). Additionally, GPLNG asks DOE to amend its existing FTA authorization (DOE/FE Order No. 3147, as amended). DOE will address the FTA portion of the Request separately pursuant to NGA section 3(c), 15 U.S.C. 717b(c).

⁸ Request at 2.

⁹ *Id.*

¹⁰ U.S. Dep’t of Energy, Policy Statement on Export Commencement Deadlines in Authorizations to Export Natural Gas to Non-Free Trade Agreement Countries, 88 FR 25,272 (Apr. 26, 2023), <https://www.energy.gov/sites/default/files/2023-06/Policy%20Statement%20on%20Export%20Commencement%20Deadlines%20in%20Authorizations%20to%20Export%20Natural%20Gas%20to%20Non-Free%20Trade%20Agreement%20Countries.pdf> [hereinafter Commencement Extension Policy].

¹¹ See Request at 2.

¹² *Id.*

¹³ *Id.* at 3.

¹⁴ *Id.* at 4.

¹⁵ *Id.* at 5–6.

¹⁶ *Id.* at 8.

¹⁷ See Request at 9.

¹⁸ *Id.* at 10.

¹⁹ *Id.*

²⁰ *Id.* at 12.

²¹ See *supra* note 1.

Request must file a motion to intervene or notice of intervention.²² The filing of comments or a protest with respect to the Request will not serve to make the commenter or protestant a party to this proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Request. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by DOE's regulations in 10 CFR part 590, including the service requirements.

Filings may be submitted using one of the following methods:

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

(2) Mailing the filing to the Office of Regulation, Analysis, and Engagement at the address listed in the **ADDRESSES** section; or

(3) Hand delivering the filing to the Office of Regulation, Analysis, and Engagement at the address listed in the **ADDRESSES** section.

For administrative efficiency, DOE prefers filings to be filed electronically. All filings must include a reference to "Docket No. 12-156-LNG" or "GPLNG Request" in the title line.

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

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

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

to this Notice, in accordance with 10 CFR 590.316.

Signed in Washington, DC, on September 23, 2024.

Amy R. Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability.

[FR Doc. 2024-22053 Filed 9-25-24; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Privacy Act of 1974; System of Records

AGENCY: Department of Energy.

ACTION: Notice of a new system of records.

SUMMARY: As required by the Privacy Act of 1974 and the Office of Management and Budget (OMB) Circulars A-108 and A-130, the Department of Energy (DOE or the Department) is publishing notice of a new Privacy Act system of records. DOE proposes to establish System of Records DOE-47 Reasonable Accommodation Requests Records. The purpose of this system of records is to assemble under a single, focused system the Department's collection and treatment of information concerning records on employees and applicants for employment who seek and receive medical and non-medical reasonable accommodations.

DATES: This System of Records Notice (SORN) will become applicable following the end of the public comment period on October 28, 2024 unless comments are received that result in a contrary determination.

ADDRESSES: Written comments should be sent to the DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW, Washington, DC 20503, and to Ken Hunt, Chief Privacy Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Rm. 8H-085, Washington, DC 20585, by facsimile at (202) 586-8151, or by email at privacy@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT: Ken Hunt, Chief Privacy Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Rm. 8H-085, Washington, DC 20585, by facsimile at (202) 586-8151, by email at privacy@hq.doe.gov, or by telephone: (240) 686-9485.

SUPPLEMENTARY INFORMATION: This notice proposes the establishment of a new system of records, DOE-47

Reasonable Accommodation Requests Records, to collect, maintain, and disseminate records on employees and applicants for employment who seek and receive medical and non-medical accommodations. The purpose of this System of Records is to assemble the Department's collection and treatment of this information together under a single, focused system. Information collected and maintained in this system includes data elements on: applicants for Federal employment who have disabilities; Federal employees with disabilities who seek accommodations to allow them to perform the essential functions of their job; Federal employees with disabilities who request or receive reasonable accommodation as required by the Department as the Rehabilitation Act of 1973 or the Americans with Disabilities Act, as amended by the Americans with Disabilities Act Amendment Act of 2008 (ADAAA); individuals who receive medical and non-medical accommodations under Title VII of the Civil Rights Act of 1964; and Federal employees or applicants for employment requesting accommodation based on a "sincerely held" religious belief, practice, or observance under the Religious Freedom Restoration Act. This system includes requests for a medical or religious accommodation. Another purpose of this system is to track and report the processing of Department-wide requests for reasonable accommodation while ensuring compliance with applicable laws and regulations, including confidentiality requirements protecting personally identifiable information individuals submit in support of accommodation requests.

SYSTEM NAME AND NUMBER:

DOE-47 Reasonable Accommodation Requests Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Systems leveraging this SORN may exist in multiple locations. All systems storing records in a cloud-based server are required to use government-approved cloud services and follow National Institute of Standards and Technology (NIST) security and privacy standards for access and data retention. Records maintained in a government-approved cloud server are accessed through secure data centers in the continental United States.

U.S. Department of Energy, Office of the General Counsel, 1000

²² Status as an intervenor in prior proceeding(s) in this docket does not continue to this proceeding evaluating GPLNG's Request, and therefore any person interested in intervening to address the Request must file a new motion to intervene (or notice of intervention, as applicable). 10 CFR 590.303.

Independence Avenue SW, Washington, DC 20585.

U.S. Department of Energy, Bonneville Power Administration, P.O. Box 3621, Portland, OR 97208.

U.S. Department of Energy, Carlsbad Field Office, 4021 National Parks Highway, P.O. Box 3090, Carlsbad, NM 88221.

U.S. Department of Energy, Environmental Management Consolidated Business Center (EMCBC), 550 Main Street, Room 7-010, Cincinnati, OH 45202.

U.S. Department of Energy, Golden Field Office, 15013 Denver West Parkway, Golden, CO 80401.

U.S. Department of Energy, Idaho Operations Office, 1955 Fremont Avenue, Idaho Falls, ID 83415.

U.S. Department of Energy, National Energy Technology Laboratory, (Pittsburgh) 626 Cochran Mill Road, Pittsburgh, PA 15236.

U.S. Department of Energy, National Energy Technology Laboratory (Morgantown), 3610 Collins Ferry Road, Morgantown, WV 26505.

U.S. Department of Energy, National Energy Technology Laboratory, (Albany) 1450 Queen Avenue SW, Albany, OR 97321.

U.S. Department of Energy, NNSA Naval Reactors Field Office, P.O. Box 109, West Mifflin, PA 15122-0109.

U.S. Department of Energy, NNSA Naval Reactors Headquarters, 1240 Isaac Hull Avenue SE, Washington Navy Yard, DC 20376-0822.

U.S. Department of Energy, NNSA Nevada Site Office, P.O. Box 98518, Las Vegas, NV 89193-8518.

U.S. Department of Energy, NNSA Service Center, NNSA Albuquerque Complex, P.O. Box 5400, Albuquerque, NM 87185-5400.

U.S. Department of Energy, Office of Science Consolidated Service Center, Oak Ridge Office, P.O. Box 2001, Oak Ridge, TN 37831.

U.S. Department of Energy, Office of Science Consolidated Service Center, Chicago Office, 9800 South Cass Avenue, Lemont, IL 60439.

U.S. Department of Energy, Office of Science and Technical Information, 1 Science Gov Way, P.O. Box 62, Oak Ridge, TN 37830.

U.S. Department of Energy, Hanford Field Office, P.O. Box 550, Richland, WA 99352.

U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29801.

U.S. Department of Energy, Southeastern Power Administration, 1166 Athens Tech Road, Elberton, GA 30635-6711.

U.S. Department of Energy, Southwestern Power Administration,

One West Third Street, Suite 1500, Tulsa, OK 74103.

U.S. Department of Energy, Strategic Petroleum Reserve Project Management Office, 900 Commerce Road East, New Orleans, LA 70123.

U.S. Department of Energy, Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228-8213.

SYSTEM MANAGER:

Director, Office of Policy, Labor and Employee Relations, Office of the Chief Human Capital Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 7101 *et seq.*; 50 U.S.C. 2401 *et seq.*; 5 U.S.C. 301; Title VII of the Civil Rights Act of 1964, as amended; Civil Rights Act of 1991; The Rehabilitation Act of 1973, 29 U.S.C. 791, as amended; The Americans with Disabilities Act of 1990, 42, U.S.C. 12101 *et seq.* (ADA); “Guidelines on Discrimination Because of Religion” and “Federal Sector Equal Employment Opportunity” Title 29 Code of Federal Regulations (CFR) Parts 1605, 1614; Executive Order 13164, Requiring Federal Agencies to Establish Procedures to Facilitate the Provision of Reasonable Accommodation (July 26, 2000); Equal Employment Opportunity Commission’s Policy Guidance on Religious Discrimination (OLC Control Number: EEOC-CVG-2021-3), July 15, 2021.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to allow the Department of Energy and its elements to collect, process, assess, and maintain records on individuals that seek medical and religious accommodations to carry out the essential functions of their job. The system will collect and maintain records pertaining to employees and applications for employment from individuals that have disabilities and employees with disabilities or other extenuating and justifiable circumstances that request or receive reasonable accommodation, including exceptions for vaccination requirements based on medical or a “sincerely held” religious belief, practice, or observance. Another purpose of the system is to track and report the processing of requests for reasonable accommodation Department-wide to comply with applicable laws and regulations and to preserve and maintain the confidentiality of information provided in support of the accommodation request. The system documents and tracks requests made to the Department

for reasonable accommodation and action taken by the Department in response to the requests. It also serves as a reference source for inquiries and responses thereto on a “need to know” basis only. Aggregate, de-identified data may be shared with Congress or other Federal agencies with an interest in employment or accommodation data and information.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include applicants for Federal employment and Federal employees that request or receive reasonable accommodation(s) on medical or religious grounds, including requests for medical accommodations made under the Rehabilitation Act of 1973, the Americans with Disabilities Act Amendments Act, requests for religious accommodations made under Title VII of the Civil Rights Act of 1964 or the Religious Freedom Restoration Act, or individuals asked to support requests for medical or religious accommodations, such as third-party medical reviewers or consultants, requestor’s physicians, or requestor’s spiritual leaders. This also includes participants in Department programs and activities, visitors at Department facilities, authorized individuals or representatives (*e.g.*, family member or attorney), who request a reasonable accommodation on behalf of an applicant for employment or employee.

CATEGORIES OF RECORDS IN THE SYSTEM:

Date of request; requestor’s first, middle, and last names; employee identification number; email address, phone number, job title, pay plan, series, and grade; requestor’s healthcare provider’s name, license number, facility address, phone number, and email address; copies of employee records, such as personnel actions or pay and leave records, necessary for processing or effecting an accommodation, supplemental medical documentation, as required; authorization for limited release of medical information; requestor’s religious or spiritual leader’s name, email address, and phone number; name, email address, and phone number of third parties involved in assisting the requestor with making the request, such as a friend, health professional, or family member, and those Department officials processing the request, including the Designated Management Official (DMO), Local Reasonable Accommodation Coordinator (LRAC), Reasonable Accommodation Program Manager (RA PM), members of the

Office of the General Counsel (OGC), third-party medical reviewer's communications, notes, and other review materials, the requestor's supervisor, and requestor's Union Representative; the name and location of applicable Servicing Human Resources Office or Shared Service Center; a description of the nature of the requestor's medical condition and its impact on their ability to perform their job; how the requestor's disability affects their major life activities; a description of the accommodation(s) requested; requestor's religious belief, practice, or observance that is the basis for their request for accommodation; a description of the timing/duration/frequency of the requested accommodation; supplemental documentation from the religious or spiritual leader, as required; description of the length of the requestor's religious belief; description of the requestor's objection to a vaccine requirement; description of whether medical or non-medical condition or religious belief precludes use of all or only certain vaccines; list of vaccines previously taken; a description of the requestor's actual or potential essential job functions; a rating of and comments concerning how the requested accommodation(s), if granted, would affect essential job functions; details from the requestor's healthcare provider concerning the impact the disability may have on key duties/privileges of employment/benefits and how the requested accommodation(s) would lessen the requestor's burden; descriptions of the nature, severity, and likely duration of the disability, activities limited by the disability, extent or degree to which the disability limits activities, the functional reason the requested accommodation(s) is required, and how the accommodation(s) will assist the requestor in applying for a job, performing essential job functions or enjoying the benefits of employment; determination for requested reasonable accommodation(s) and statement of rationale for the determination; documentation concerning denials, reconsideration, administrative closure, expenses related to the accommodation, appeal rights, interim accommodation, and requests for and limitations on a reassignment as reasonable accommodation of last resort; or other management reports/assessments, checklists, notes, and other relevant correspondence.

RECORD SOURCE CATEGORIES:

The records are provided by the individual making the request ("the

requestor"), third-parties acting on behalf of the requestor, by Department personnel involved in processing or adjudicating the request (including supervisors, reasonable accommodation coordinators, equal employment opportunity (EEO) specialists, employee relation specialists, attorneys, medical review personnel, and contracting officers and their representatives), third-party claims' reviewers or consultants, and by others furnishing records pertinent to the request (such as, the requestor's healthcare provider, religion/spiritual leader, or technical experts).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Any disclosures of information from this System of Records will be compatible with the purpose for which the Office of the Chief Human Capital Officer (HC) collects and maintains the information. Information from this system may be disclosed to the individual to whom it pertains, or: (1) to the individual's next-of kin, parent, guardian, or emergency contact; (2) to the public about an individual's involvement with HC with the written consent of that individual; or (3) in accordance with standard routine uses as follows:

1. A record from this system may be disclosed as a routine use to supervisors and managers who need to know the necessary work restrictions and about the necessary approved accommodation(s).

2. A record from this system may be disclosed as a routine use to safety, medical, emergency personnel if the disability may require emergency treatment.

3. A record from this system may be disclosed as a routine use to government officials who investigate the reasonable accommodation program for compliance with and nondiscrimination under section 501 of the Rehabilitation Act.

4. A record from this system may be disclosed as a routine use to workers' compensation offices or insurance carriers.

5. A record from this system may be disclosed as a routine use to officials at a Federal, State, or local agency, such as the Equal Employment Opportunity Commission, that is part of the review of the issue(s) raised in the accommodation. A record from this system may be disclosed as a routine use to the appropriate local, state, tribal, or other Federal agency when records alone or in conjunction with other information, indicates a violation or potential violation of law whether civil,

criminal, or regulatory in nature, and whether arising by general statute or particular program pursuant thereto.

6. A record from this system may be disclosed as a routine use for the purpose of an investigation, settlement of claims, or the preparation and conduct of litigation to (1) persons representing the Department in the investigation, settlement or litigation, and to individuals assisting in such representation; (2) others involved in the investigation, settlement, and litigation, and their representatives and individuals assisting those representatives; (3) witnesses, potential witnesses, or their representatives and assistants; and (4) any other persons who possess information pertaining to the matter when it is relevant and necessary to obtain information or testimony relevant to the matter.

7. A record from this system may be disclosed as a routine use in court or administrative proceedings to the tribunals, counsel, other parties, witnesses, and the public (in publicly available pleadings, filings, or discussion in open court) when such disclosure: (1) is relevant to, and necessary for, the proceeding; (2) is compatible with the purpose for which the Department collected the records; and (3) the proceedings involve:

a. The Department, its predecessor agencies, current or former contractor of the Department, or other United States Government agencies and their components, or

b. A current or former employee of the Department and its predecessor agencies, current or former contractors of the Department, or other United States Government agencies and their components, who is acting in an official capacity or in any individual capacity where the Department or other United States Government agency has agreed to represent the employee.

8. A record from this system may be disclosed as a routine use to DOE contractors in performance of their contracts, and their officers and employees who have a need for the record in the performance of their duties. Those provided information under this routine use are subject to the same limitations applicable to Department officers and employees under the Privacy Act.

9. A record from this system may be disclosed as a routine use to appropriate agencies, entities, and persons when (1) the Department suspects or has confirmed that there has been a breach of the System of Records; (2) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to

individuals, DOE (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

10. A record from this system may be disclosed as a routine use to another Federal agency or Federal entity, when the Department determines that information from this System of Records is reasonably necessary to assist the recipient agency or entity in (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.

11. A record from this system may be disclosed as a routine use to a Member of Congress submitting a request involving a constituent when the constituent has requested assistance from the member concerning the subject matter of the record. The Member of Congress must provide a copy of the constituent's signed request for assistance.

12. A record from this system may be disclosed as a routine use to an authorized appeal grievance examiner, formal complaints examiner, administrative judge, equal opportunity investigator, arbitrator or other duly authorized official engaged in investigation or settlement of a grievance, complaint or appeal filed by an employee.

13. A record from this system may be disclosed as a routine use to such recipients and under such circumstances and procedures as are mandated by Federal statute, executive order, or treaty.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system are on paper or in digital or other electronic form. Digital and other electronic images are stored on a storage area network in a secured environment. Records, whether paper or electronic, may be stored in a separate, secure location at the Department of Energy Headquarters or at Department field sites.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name of the requester, employing organizational

element, or any unique identifying number assigned to the request, if applicable.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Retention and disposition of these records is in accordance with the National Archives and Records Administration approved records disposition schedule with a retention of 3 years.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Electronic records may be secured and maintained on a cloud-based software server and operating system that resides in Federal Risk and Authorization Management Program (FedRAMP) and Federal Information Security Modernization Act (FISMA) hosting environment. Data located in the cloud-based server is firewalled and encrypted at rest and in transit. The security mechanisms for handling data at rest and in transit are in accordance with DOE encryption standards. Records are protected from unauthorized access through the following appropriate safeguards:

- *Administrative:* Access to all records is limited to lawful government purposes only, with access to electronic records based on role and either two-factor authentication or password protection. The system requires passwords to be complex and to be changed frequently. Users accessing system records undergo frequent training in Privacy Act and information security requirements. Security and privacy controls are reviewed on an ongoing basis.

- *Technical:* Computerized records systems are safeguarded on Departmental networks configured for role-based access based on job responsibilities and organizational affiliation. Privacy and security controls are in place for this system and are updated in accordance with applicable requirements as determined by NIST and DOE directives and guidance.

- *Physical:* Computer servers on which electronic records are stored are located in secured Department facilities, which are protected by security guards, identification badges, and cameras. Paper copies of all records are locked in file cabinets, file rooms, or offices and are under the control of authorized personnel. Access to these facilities is granted only to authorized personnel and each person granted access to the system must be individual authorized to use or administer the system.

RECORD ACCESS PROCEDURES:

The Department follows the procedures outlined in 10 CFR 1008.4. Valid identification of the individual making the request is required before information will be processed, given, access granted, or a correction considered, to ensure that information is processed, given, corrected, or records disclosed or corrected only at the request of the proper person.

CONTESTING RECORD PROCEDURES:

Any individual may submit a request to the System Manager and request a copy of any records relating to them. In accordance with 10 CFR 1008.11, any individual may appeal the denial of a request made by him or her for information about or for access to or correction or amendment of records. An appeal shall be filed within 90 calendar days after receipt of the denial. When an appeal is filed by mail, the postmark is conclusive as to timeliness. The appeal shall be in writing and must be signed by the individual. The words "PRIVACY ACT APPEAL" should appear in capital letters on the envelope and the letter. Appeals relating to DOE records shall be directed to the Director, Office of Hearings and Appeals (OHA), 1000 Independence Avenue SW, Washington, DC 20585.

NOTIFICATION PROCEDURES:

In accordance with the DOE regulation implementing the Privacy Act, 10 CFR part 1008, a request by an individual to determine if a system of records contains information about themselves should be directed to the U.S. Department of Energy, Headquarters, Privacy Act Officer. The request should include the requester's complete name and the time period for which records are sought.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This notice proposes to establish DOE-47 Reasonable Accommodation Requests Records as a new system of records. There has been no previous publication in the **Federal Register** pertaining to this system of records.

Signing Authority

This document of the Department of Energy was signed on September 20, 2024, by Ann Dunkin, Senior Agency Official for Privacy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with

requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on September 23, 2024.

Treena V. Garrett,

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

[FR Doc. 2024–22084 Filed 9–25–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–468–000]

Texas Gas Transmission, LLC, Gulf South Pipeline Company, LLC; Notice of Schedule for the Preparation of an Environmental Assessment for the Eunice Reliability and Lake Charles Supply Project

On May 8, 2024, Texas Gas Transmission, LLC (Texas Gas) and Gulf South Pipeline Company, LLC (Gulf South) filed an application in Docket No. CP24–468–000 requesting a Certificate of Public Convenience and Necessity and abandonment authorization pursuant to Sections 7(b) and 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations to construct, operate and abandon certain natural gas pipeline facilities. The proposed project is known as the Eunice Reliability and Lake Charles Supply Project (Project) and would: (1) replace five existing reciprocating compressor units with two new Solar T70 and T60 units at the Texas Gas existing Eunice Compressor Station in Acadia Parish, Louisiana; and (2) install overpressure protection at its existing Woodlawn Junction in Jefferson Davis Parish, Louisiana. The Project would create 120,000 dekatherms per day (Dth/d) of new transportation capacity on Texas Gas' system that would be leased to Gulf South to meet its customers' needs in the Lake Charles area, including an electric utility and two natural gas marketers.

On May 21, 2024, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing Federal authorizations of the requirement to complete all necessary reviews and to

reach a final decision on a request for a Federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.¹ The EA will be issued for a 30-day comment period.

Schedule for Environmental Review

Issuance of EA—January 31, 2025
90-day Federal Authorization Decision
Deadline²—May 1, 2025

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Project would consist of the following facilities:

- replace four 1,100 horsepower and one 2,250 horsepower reciprocating units with one 8,968 horsepower Solar T–70 gas-fired, turbine-driven unit and one 6,391 horsepower Solar T60 gas-fired, turbine-driven unit, and appurtenances at the Eunice Compressor Station in Acadia Parish, Louisiana; and
- install overpressure protection at the existing Woodlawn Junction in Jefferson Davis Parish, Louisiana.

Background

On June 10, 2024, the Commission Issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Eunice Reliability and Lake Charles Supply Project* (Notice of Scoping). The Notice of Scoping was sent to affected landowners; Federal, State, and local government agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. In response to the Notice of Scoping, the Commission received four comments from the Louisiana Ecological Services Office,

¹ In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1725459309. 40 CFR 1501.5(c)(4) (2024).

² The Commission's deadline applies to the decisions of other Federal agencies, and State agencies acting under federally delegated authority, that are responsible for Federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by Federal law.

U.S. Environmental Protection Agency—Region 6, Choctaw Nation of Oklahoma, and Restore (Restore Explicit Symmetry To Our Ravaged Earth). All substantive comments will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (www.ferc.gov). Using the “eLibrary” link, select “General Search” from the eLibrary menu, enter the selected date range and “Docket Number” excluding the last three digits (*i.e.*, CP24–468–000), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: September 20, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–22080 Filed 9–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Docket No. RP24–971–000]****Vector Pipeline L.P.; Notice of Initiation of Section 5 Proceeding**

On September 19, 2024, the Commission issued an order in Docket No. RP24–971–000, pursuant to section 5 of the Natural Gas Act (NGA), 15 U.S.C. 717d, instituting an investigation into whether the rates currently charged by Vector Pipeline L.P. are just and reasonable. *Vector Pipeline L.P.*, 188 FERC ¶ 61,184 (2024).

Any interested person desiring to be heard in Docket No. RP24–971–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2024), within 30 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>) using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFile" link at <http://www.ferc.gov>. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: September 19, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–21998 Filed 9–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Docket No. RM24–9–000]****Alliance for Tribal Clean Energy; Notice of Tribal Consultation**

On August 9, 2024, the Alliance for Tribal Clean Energy (ATCE), pursuant to Rule 207(a)(4) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(4) (2024), filed a petition requesting that the Commission conduct an expedited rulemaking to revise the *pro forma* Large Generator Interconnection Procedures (LGIP) to defer the time at which certain "Tribal Energy Development Organizations" must post commercial readiness deposits and partially exempt them from potential withdrawal penalties.¹

Because the petition seeks to have the Commission institute a rulemaking proceeding that involves issues that would uniquely affect Tribes,² the Commission will conduct Tribal consultation with federally recognized Tribes on whether to conduct a rulemaking to revise the *pro forma* LGIP as requested by ATCE. Specifically, the

Commission will consult with Tribes on:

1. Whether to propose to adopt a definition of "Tribal Energy Development Organizations," and perspectives on the definition.

2. Whether to propose to permit those Tribal Energy Development Organizations to defer paying commercial readiness deposits for generator interconnection requests until the execution of a Large Generator Interconnection Agreement.

3. Whether to propose to exempt those Tribal Energy Development Organizations from paying the generator interconnection request withdrawal penalties required by section 3.7.1.1(a) of the *pro forma* LGIP.

4. Whether to propose to permit those Tribal Energy Development Organizations withdrawing generator interconnection requests during the timeframes in sections 3.7.1.1(b) and 3.7.1.1(c) of the *pro forma* LGIP to pay a penalty equal to the actual study costs incurred by the withdrawing customer at the time of withdrawal, capped at \$150,000.

5. What challenges Tribes face when pursuing generator interconnection, including the impacts of the commercial readiness deposits and withdrawal penalties set forth in the *pro forma* LGIP.

6. Whether energy projects developed by Tribes are more likely to proceed to commercial operation than projects proposed by other developers? And if so, please share why.

The Tribal consultation will be conducted in accord with the Commission's *Policy Statement on Consultation with Indian Tribes in Commission Proceedings*, Order No. 635, 104 FERC ¶ 61,108 (2003), 18 CFR 2.1c. The Policy Statement states that the Commission will engage Tribes in high-level meetings to discuss general matters of importance, such as those that uniquely affect Tribes.

Tribal consultation will be conducted in two virtual, web-based meetings on October 28, 2024, and November 4, 2024, from 2 p.m.–4 p.m. ET. A call-in option will also be provided. Senior staff from the Office of Energy Policy and Innovation, the Office of Energy Market Regulation, and the Office of the General Counsel will participate in the consultations.

Tribal government leaders or designated representatives interested in participating in consultation on this matter, or who have questions at this time, may contact the Commission by emailing tribalrelations@ferc.gov.

Interested persons may access the contents of this docket via the internet

¹ See *Notice of Petition for Rulemaking and Intent to Hold Tribal Consultation Meetings*, Docket No. RM24–9–000 (September 3, 2024).

² "Tribes" and "Tribal" are used herein to refer to federally recognized Indian Tribes as referenced in the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 5130.

through the Commission's online "eLibrary" at <http://www.eliibrary.ferc.gov/> by entering "RM24-9" in the docket number field. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TTY, (202) 502-8659.

Dated: September 19, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-21997 Filed 9-25-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2411-030]

Eagle Creek Schoolfield, LLC, City of Danville; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

- a. *Type of Application:* New Major License.
- b. *Project No.:* 2411-030.
- c. *Date filed:* July 29, 2022.
- d. *Applicant:* Eagle Creek Schoolfield, LLC and City of Danville.
- e. *Name of Project:* Schoolfield Hydroelectric Project (Schoolfield Project or project).
- f. *Location:* The project is located on the Dan River at approximately river mile 60.1 in the county of Pittsylvania, near the City of Danville, Virginia.
- g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)-825(r).
- h. *Applicant Contact:* Jody Smet, Vice President, Engineering and Regulatory Affairs, Eagle Creek Renewable Energy, LLC, 7315 Wisconsin Avenue, Suite 1100W, Bethesda, Maryland 20814; phone at (804) 382-1764 or email at jody.smet@eaglecreekre.com; Joyce Foster, Director, Licensing and Compliance, Eagle Creek Renewable Energy, LLC, 7315 Wisconsin Avenue, Suite 1100W, Bethesda, Maryland 20814; phone at (804) 338-5110 or email at Joyce.Foster@eaglecreekre.com; and Mr. W. Clarke Whitfield, Junior, City Attorney, City of Danville, 427 Patton Street, Room 421, Danville, Virginia 24541; phone at (434) 799-5122 or email at whitfcc@danvilleva.gov.
- i. *FERC Contact:* Claire Rozdilski at (202) 502-8259; or email at claire.rozdilski@ferc.gov.

j. *Deadline for filing comments, recommendations, terms and conditions, and prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments, recommendations, terms and conditions, and prescriptions using the Commission's eFiling system at <https://ferconline.ferc.gov/FERCOOnline.aspx>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please send a paper copy via U.S. Postal Service to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Schoolfield Hydroelectric Project (P-2411-030).

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted and is ready for environmental analysis at this time.

1. *The project facilities consist of:* (1) a 910-foot-long, 26.5-foot-high curved ogee-type concrete spillway dam with a crest elevation of 434.7 feet National Geodetic Vertical Datum of 1929 (NGVD29) and topped with 3-foot-high wooden flashboards; (2) an impoundment having a surface area of 287 acres and a gross storage capacity of approximately 1,952 acre-feet at the project's normal maximum water surface elevation of 437.7 feet NGVD29; (3) a 224-foot-long by 35-foot-wide brick and concrete powerhouse that contains three identical 1.5-megawatt (MW) generating units (each generating unit is

connected to two identical propeller-type turbine units with a rated capacity of 1,006 horsepower each) for a total installed capacity of 4.5 MW; (4) a 72-foot-long headwall between the dam and the powerhouse with six low-level sluice gates and a non-operating fish ladder; (5) a tailrace that is approximately 160 feet long and 220 feet wide and separated from main river flows by a concrete wall; (6) a substation; (7) generator leads and a step-up transformer; and (8) appurtenant facilities.

The Schoolfield Project is operated in run-of-river mode, whereby outflow from the project approximates inflow, which may be suspended during reservoir drawdown and refilling for inspection of the City of Danville's water supply intakes, which occurs on an as needed basis. During normal operation, a continuous minimum flow of 300 cubic feet per second, or inflow if less, is released downstream. The average annual generation at the project was 15,220 MW-hours from 2017 through 2020.

m. This filing may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support.

All filings must (1) bear in all capital letters the title "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicants and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicants. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding in accordance with 18 CFR 4.34(b) and 385.2010.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and

others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595, or at OPP@ferc.gov.

You may also register online at <http://www.ferc.gov/docs-filing/>

esubscription.asp to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *The applicant must file no later than 60 days from the issuance date of this notice:* (1) copy of the water quality certification; (2) a copy of the request for certification, including proof of the date

on which the certifying agency received the request; or (3) evidence of a waiver of water quality certification.

o. *Procedural schedule:* The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Milestones	Target date
Deadline for filing comments, recommendations, terms and conditions, and prescriptions	November 18, 2024.
Deadline for filing reply comments	January 2, 2025.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

Dated: September 19, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-21994 Filed 9-25-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 96-048]

Pacific Gas and Electric Company; Notice of Intent To Prepare an Environmental Assessment

On November 24, 2020, Pacific Gas and Electric Company (PG&E) filed a relicense application for the 162.72-megawatt Kerckhoff Hydroelectric Project No. 96 (project). The project is located on the San Joaquin River in Fresno and Madera Counties, California, about 25 miles northeast of the city of Fresno. The project currently occupies 180.5 acres of Federal land administered by the U.S. Forest Service (Forest Service), 92.9 acres of Federal land managed by the U.S. Bureau of Land Management (BLM), and 54.7 acres of land managed by the U.S. Bureau of Reclamation (BOR). As proposed, the project would occupy 67.2 less acres of Federal land administered by the Forest Service, an additional 3.1 acres of land managed by the BLM, and an additional 1.8 acre of land managed by the BOR. As part of its relicensing proposal, PG&E proposes to retire the project K1 Powerhouse (one of two project powerhouses), thereby decreasing the generating capacity of the project from 162.72 to 140 megawatts.

In accordance with the Commission's regulations, on June 27, 2024, Commission staff issued a notice that

the project was ready for environmental analysis (REA Notice). Based on the information in the record, including comments filed on the REA Notice, staff does not anticipate that licensing the project would constitute a major Federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an Environmental Assessment (EA) on the application to relicense the project.¹

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

The application will be processed according to the following schedule. The EA will be issued for a 30-day comment period. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA.	September 19, 2025.

Any questions regarding this notice may be directed to Evan Williams at (202) 502-8462 or evan.williams@ferc.gov.

¹ In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-172537975. 40 CFR 1501.5(c)(4) (2024).

Dated: September 20, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-22082 Filed 9-25-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10615-058]

Tower Kleber Limited Partnership; Notice of Intent To Prepare an Environmental Assessment

On April 28, 2022, Tower Kleber Limited Partnership filed a relicense application for the 1.76-megawatt Tower and Kleber Hydroelectric Project No. 10615. The project is located on the Black River in Cheboygan County, Michigan.

In accordance with the Commission's regulations, on May 10, 2024, Commission staff issued a notice that the project was ready for environmental analysis (REA Notice). Based on the information in the record, including comments filed on the REA Notice, staff does not anticipate that licensing the project would constitute a major federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an Environmental Assessment (EA) on the application to relicense the project.¹

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help

¹ In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-1725361895. 40 CFR 1501.5(c)(4) (2024).

members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or *OPP@ferc.gov*.

The application will be processed according to the following schedule. The EA will be issued for a 30-day comment period. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA	April 30, 2025.

Any questions regarding this notice may be directed to Arash Barsari at (202) 502-6207 or *Arash.JalaliBarsari@ferc.gov*.

Dated: September 20, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-22092 Filed 9-25-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC24-122-000.
Applicants: PGR Holdco, LP, Allora Solar, LLC, PGR 2021 Lessee 19, LLC, Apex Solar, LLC, Beulah Solar, LLC, PGR 2021 Lessee 2, LLC, TWE Bowman Solar Project, LLC, PGR Lessee L, LLC, Bulldog Solar, LLC, PGR 2021 Lessee 9, LLC, Cabin Creek Solar, LLC, PGR 2021 Lessee 12, LLC, Cane Creek Solar, LLC, PGR 2022 Lessee 4, LLC, Centerfield Cooper Solar, LLC, PGR Lessee O, LLC, PGR 2021 Lessee 17, LLC, Fresh Air Energy XXIII, LLC, PGR 2022 Lessee 2, LLC, Eastover Solar, LLC, Glover Creek Solar, LLC, PGR 2022 Lessee 9, LLC, Gunsight Solar, LLC, PGR 2021 Lessee 15, LLC, Highest Power Solar, LLC, PGR 2021 Lessee 7, LLC, Landrace Holdings, LLC, PGR 2021 Lessee 18, LLC, Lick Creek Solar, LLC, PGR 2021 Lessee 5, LLC, Peony Solar, LLC, Phobos Solar, LLC, PGR 2021 Lessee 11, LLC, Sonny Solar, LLC, PGR 2021 Lessee 13, LLC, Stanly Solar, LLC, PGR 2021 Lessee 1, LLC, Sugar Solar, LLC, PGR 2020 Lessee 8, LLC, Trent River Solar, LLC, Trent River Solar Mile Lessee, LLC, Two

Hearted Solar, LLC, Virginia Line Solar, LLC, PGR 2022 Lessee 1, LLC, Moonshot Solar, LLC, PGR 2022 Lessee 5, LLC, West River Solar, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of PGR Holdco, LP.

Filed Date: 9/16/24.

Accession Number: 20240916-5153.

Comment Date: 5 p.m. ET 10/7/24.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG24-291-000.

Applicants: Prairie Center Energy LLC.

Description: Prairie Center Energy LLC submits Corrected Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 9/19/24.

Accession Number: 20240919-5144.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: EG24-292-000.

Applicants: Henrietta BESS LLC.

Description: Henrietta BESS LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 9/19/24.

Accession Number: 20240919-5034.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: EG24-293-000.

Applicants: Hanford BESS LLC.

Description: Hanford BESS LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 9/19/24.

Accession Number: 20240919-5036.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: EG24-294-000.

Applicants: Malaga BESS LLC.

Description: Malaga BESS LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 9/19/24.

Accession Number: 20240919-5037.

Comment Date: 5 p.m. ET 10/10/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER24-2223-000.

Applicants: Roundtop Energy LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 9/19/24.

Accession Number: 20240919-5132.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24-2224-000.

Applicants: Beaver Dam Energy LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 9/19/24.

Accession Number: 20240919-5139.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24-2225-000.

Applicants: Alpaca Energy LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 9/19/24.

Accession Number: 20240919-5142.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24-2226-000.

Applicants: Milan Energy LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 9/19/24.

Accession Number: 20240919-5143.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24-2227-000.

Applicants: Wolf Run Energy LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 9/19/24.

Accession Number: 20240919-5166.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24-2228-000.

Applicants: Oxbow Creek Energy LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 9/19/24.

Accession Number: 20240919-5178.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24-2669-001.

Applicants: CleanChoice Power Solutions, LLC.

Description: Tariff Amendment:

Amendment to 1 to be effective 9/1/2024.

Filed Date: 9/18/24.

Accession Number: 20240918-5154.

Comment Date: 5 p.m. ET 9/30/24.

Docket Numbers: ER24-3075-000.

Applicants: Florida Power & Light Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 351 FPL and FMPA Agreement for Dynamic Scheduling Services to be effective 11/18/2024.

Filed Date: 9/18/24.

Accession Number: 20240918-5148.

Comment Date: 5 p.m. ET 10/9/24.

Docket Numbers: ER24-3076-000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of WMPA SA No. 6111, AD1-016 to be effective 11/19/2024.

Filed Date: 9/19/24.

Accession Number: 20240919-5035.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24-3077-000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of ICSA, Service Agreement No. 5862, Queue No. AB2-070 to be effective 11/19/2024.

Filed Date: 9/19/24.

Accession Number: 20240919-5041.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24-3078-000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of WMPA, SA

No. 6114, Queue AD1–129 to be effective 11/19/2024.

Filed Date: 9/19/24.

Accession Number: 20240919–5043.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24–3079–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Service Agreement No. 424, E&P Agreement between APS & APS to be effective 8/21/2024.

Filed Date: 9/19/24.

Accession Number: 20240919–5086.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24–3080–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 217, Exhibit B Revisions to be effective 11/21/2024.

Filed Date: 9/19/24.

Accession Number: 20240919–5087.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24–3081–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original GIA Service Agreement No. 7348, AG1–495 to be effective 8/20/2024.

Filed Date: 9/19/24.

Accession Number: 20240919–5111.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24–3082–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii): FP&L Transmission Interconnection Agreement Amendment Filing to be effective 8/21/2024.

Filed Date: 9/19/24.

Accession Number: 20240919–5115.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24–3083–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2024–09–19_SA 4276 NIPSCO-Monroe Power 1st Rev GIA (J1355) to be effective 9/11/2024.

Filed Date: 9/19/24.

Accession Number: 20240919–5118.

Comment Date: 5 p.m. ET 10/10/24.

Docket Numbers: ER24–3084–000.

Applicants: San Diego Gas & Electric.
Description: § 205(d) Rate Filing: Service Agreement No. 68 to be effective 6/18/2024.

Filed Date: 9/19/24.

Accession Number: 20240919–5129.

Comment Date: 5 p.m. ET 10/10/24.

The filings are accessible in the Commission's eLibrary system ([https://](https://elibrary.ferc.gov/idmws/search/fercgensearch.asp)

elibrary.ferc.gov/idmws/search/fercgensearch.asp) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: September 19, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–21991 Filed 9–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC24–21–000]

Commission Information Collection Activities (FERC–588) Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–588, Emergency Natural Gas Transportation, Sale, and Exchange

Transactions (OMB Control Number 1902–0144). The 60-day notice comment period ended on September 18, 2024, and no comments were received.

DATES: Comments on the collection of information are due October 28, 2024.

ADDRESSES: Send written comments on FERC–588 to OMB through www.reginfo.gov/public/do/PRAMain. Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number (1902–0144) in the subject line of your comments. Comments should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain.

Please submit copies of your comments to the Commission. You may submit copies of your comments (identified by Docket No. IC24–21–000) by one of the following methods:

Electronic filing through <https://www.ferc.gov>, is preferred.

- **Electronic Filing:** Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

- For those unable to file electronically, comments may be filed by USPS mail or by other delivery methods:

- **Mail via U.S. Postal Service Only:** Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- **All other delivery methods:** Federal Energy Regulatory Commission, Secretary of the Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at www.reginfo.gov/public/do/PRAMain. Using the search function under the “Currently Under Review” field, select Federal Energy Regulatory Commission; click “submit,” and select “comment” to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: <https://www.ferc.gov/ferc-online/overview>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <https://www.ferc.gov/ferc-online/overview>.

FOR FURTHER INFORMATION CONTACT:

Kayla Williams may be reached by email at DataClearance@FERC.gov, telephone at (202) 502–6468.

SUPPLEMENTARY INFORMATION:

Title: FERC–588 (Emergency Natural Gas Transportation, Sale, and Exchange Transactions).

OMB Control No.: 1902–0144.

Type of Request: Three-year extension of the FERC–588 information collection requirements with no changes to the current reporting and recordkeeping requirements.

Abstract: FERC–588 is an existing information collection consisting of filing requirements and notice procedures applicable to responses to natural gas emergency circumstances. Two sets of information collection activities pertain to such responses.

One set applies to responses by a jurisdictional “natural-gas company,” *i.e.*, a person engaged in the transportation of natural gas in interstate commerce, or the sale in interstate commerce of such gas for resale.¹ Section 7(c)(1)(A) of the Natural Gas Act ² requires any natural-gas company to obtain a certificate of public

convenience and necessity issued by the Commission before engaging in the transportation or sale of natural gas in interstate commerce, or undertaking the construction or extension of any facilities for the transportation or sale of natural gas in interstate commerce. Under 18 CFR 157.17, a jurisdictional natural-gas company may file an application for a temporary certificate authorizing the construction and operation of extensions of existing facilities, interconnections of pipeline systems, or sales of natural gas that may be required to assure maintenance of adequate service, or to service particular customers.

The other set of responses to a natural gas emergency, at 18 CFR part 284 subpart I, exempts a person who engages in an emergency natural gas transaction in interstate commerce from the certificate requirements of section 7 of the Natural Gas Act.³ The term “emergency natural gas transaction” is

defined at 18 CFR 284.262 as the sale, transportation, or exchange of natural gas (including the construction and operation of necessary facilities) conducted pursuant to this subpart, that is:

- (1) Necessary to alleviate an emergency; and
- (2) Not anticipated to extend for more than 60 days in duration.

A non-jurisdictional company that engages in an emergency natural gas transactions must file information with the Commission under 18 CFR 284.270, so that the Commission may ensure compliance with relevant legal requirements.

Types of Respondent: Providers and recipients of assistance in natural gas emergency circumstances.

*Estimate of Annual Burden:*⁴ The Commission estimates the total annual burden and cost ⁵ for this information collection in the following table:

A. Number of respondents	B. Annual number of responses per respondent	C. Total number of responses (Col. A × Col. B)	D. Average hr. burden and cost per response	E. Total annual hr. burden and cost (Col. C × Col D)
10	3	30	10 hrs; \$1,000	300 hrs.; \$30,000.

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency’s estimate of the burden and cost 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 collection; and (4) 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.

Dated: September 20, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–22091 Filed 9–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

**Federal Energy Regulatory
Commission**

[Docket No. RM01–5–000]

**Electronic Tariff Filings; Notice of
Posting of Revised Type of Filing and
Validation Error Codes for Testing**

Take notice that revised Type of Filing and Validation Error Codes have been posted for testing the compliance filing revisions to be implemented November 25, 2024, as indicated in the September 6, 2024, notice in this docket. The revised codes will ensure that parties differentiate between (1) compliance filings in a current proceeding for which the filer has a filing identifier, which are assigned a sub-docket, and (2) compliance filings, such as compliance with complaint orders and rulemakings, where the filer has no existing filing identifier and therefore must establish a new docket. New filing codes also will be assigned to allow utilities to distinguish baseline

rate change filings from baseline initial rate filings.

Under the eTariff XML schema, filers that are making a filing related to an existing proceeding with a Filing Identifier must include an Associated Filing Identifier at the Filing level for the filing to receive a sub-docket. In this situation, filers must submit the filing using the compliance type category and must include an associated filing identifier at the Filing level, so they are assigned a sub-docket of the original docket. Failure to include the associated filing identifier will result in a rejection of the filing (Error code 28—An Associated Filing Identifier is required at filing level.). Type of Filing Codes designated under the compliance new type category apply to filings that will receive a new docket number. If the filing using these codes includes an associated filing identifier at the Filing level, the filing be rejected (Error code 187—This type of filing code establishes a new docket, so the associated filing identifier is not needed).

¹ The definition of “natural-gas company” is at 15 U.S.C. 717a(6).

² 15 U.S.C. 717f(c)(1)(A).

³ 18 CFR 284.261.

⁴ “Burden” is the total time, effort, or financial resources expended by persons to generate,

maintain, retain, or disclose or provide information to or for a federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

⁵ The Commission staff believes that industry is similarly situated to the Commission in terms of

cost for wages and benefits. Based on FERC’s current annual average cost of \$207,786 (for salary plus benefits) for a full-time equivalent, the average hourly cost is \$100/hour. Therefore, the hourly cost used in the burden calculation is \$100.

Starting on September 30, 2024, the currently deployed test sandbox will include the revised Type of Filing and Validation Error Codes. These codes are for testing purposes only; they cannot be used to make official tariff filings through eFiling.

The revised Type of Filing and Validation Error Codes, along with a marked version highlighting the revisions, will be posted at the same eLibrary Accession Number as this Notice. The posting also will include all the files associated with the addition of the lead applicant field in the XML schemas and the addition of the flexibility to file tariff records using Microsoft Word and Excel formats.

Questions on these changes should be directed to: Michael Goldenberg at Michael.Goldenberg@ferc.gov or James Sarikas at James.Sarikas@ferc.gov.

Dated: September 20, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024–22083 Filed 9–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP24–1069–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: 4(d) Rate Filing: Negotiated Rates—Yankee Gas to Emera off 9–20–24 to be effective 9/20/2024.

Filed Date: 9/20/24.

Accession Number: 20240920–5030.

Comment Date: 5 p.m. ET 10/2/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests,

service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: September 20, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024–22087 Filed 9–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–518–000]

Panhandle Eastern Pipe Line Company, LP; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on September 12, 2024, Panhandle Eastern Pipe Line Company, LP (Panhandle), 1300 Main Street, Houston, Texas 77002, filed in the above referenced docket a prior notice request pursuant to sections 157.205 and 157.208(f)(2) of the Commission's regulations under the Natural Gas Act (NGA), and Panhandle's blanket certificate issued in Docket No. CP83–83–000, for authorization to reduce the maximum allowable operating pressure (MAOP) of its 1.65-mile-long, six-inch-diameter Mexico Lateral located in Audrain County, Missouri (Project). Specifically, Panhandle proposes to lower the MAOP of the Mexico Lateral from 960 pounds per square inch gauge (psig) to 900 psig, thus making the requirements for inspection of the Mexico Lateral not applicable, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this

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

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

Any questions concerning this request should be directed to Blair Lichtenwalter, Senior Director of Certificates, Panhandle Eastern Pipe Line Company, LP, 1300 Main Street, Houston, Texas 77002, by telephone at (713) 989–2605, or by email at blair.lichtenwalter@energytransfer.com.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on November 18, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Protests

Pursuant to section 157.205 of the Commission's regulations under the

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

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,³ and must be submitted by the protest deadline, which is November 18, 2024. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

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

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁴ and the regulations under the NGA⁵ by the intervention deadline for the project, which is November 18, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to-intervene.asp>.

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for

being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before November 18, 2024. *The filing of a comment alone will not serve to make the filer a party to the proceeding.* To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP24-518-000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Protest", "Intervention", or "Comment on a Filing"; or⁶

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP24-518-000.

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

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

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available

to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail at: Blair Lichtenwalter, Senior Director of Certificates, Panhandle Eastern Pipe Line Company, LP, 1300 Main Street, Houston, Texas 77002, or by email at blair.lichtenwalter@energytransfer.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

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

Dated: September 19, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-21993 Filed 9-25-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR24-97-000.

Applicants: Northern Indiana Public Service Company.

Description: § 284.123 Rate Filing: Revisions to NIPSCO's SOC to be effective 8/20/2024.

Filed Date: 9/19/24.

Accession Number: 20240919-5021.

Comment Date: 5 p.m. ET 10/10/24.

¹ 18 CFR 157.205.

² Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

³ 18 CFR 157.205(e).

⁴ 18 CFR 385.214.

⁵ 18 CFR 157.10.

⁶ Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

Docket Numbers: RP24–1066–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—Arkansas Electric Cooperative Corporation to be effective 10/1/2024.
Filed Date: 9/18/24.
Accession Number: 20240918–5138.
Comment Date: 5 p.m. ET 9/30/24.
Docket Numbers: RP24–1067–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Remove Terminated Negotiated Rate Agreement—10/19/2024 to be effective 10/19/2024.
Filed Date: 9/19/24.
Accession Number: 20240919–5022.
Comment Date: 5 p.m. ET 10/1/24.
Docket Numbers: RP24–1068–000.
Applicants: Sabine Pipe Line LLC.
Description: § 4(d) Rate Filing: Normal filing Oct 2024—7.26–4.10 to be effective 10/1/2024.
Filed Date: 9/19/24.
Accession Number: 20240919–5049.
Comment Date: 5 p.m. ET 10/1/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP24–1046–001.
Applicants: Scout V Hugoton Gathering, LP.
Description: Tariff Amendment: Amendment to be effective 10/4/2024.
Filed Date: 9/18/24.
Accession Number: 20240918–5094.
Comment Date: 5 p.m. ET 9/30/24.

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

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

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful

public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: September 19, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024–21992 Filed 9–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER24–165–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2024–09–20_A Additional Compliance for Order 895 Credit Information Sharing to be effective 7/26/2024.

Filed Date: 9/20/24.
Accession Number: 20240920–5010.
Comment Date: 5 p.m. ET 10/11/24.
Docket Numbers: ER24–2534–001.
Applicants: Gravel Pit Solar III, LLC.
Description: Tariff Amendment:

Response to Deficiency Letter to be effective 9/11/2024.

Filed Date: 9/20/24.
Accession Number: 20240920–5076.
Comment Date: 5 p.m. ET 10/11/24.
Docket Numbers: ER24–2535–001.
Applicants: Gravel Pit Solar IV, LLC.
Description: Tariff Amendment:

Response to Deficiency Letter to be effective 9/11/2024.

Filed Date: 9/20/24.
Accession Number: 20240920–5078.
Comment Date: 5 p.m. ET 10/11/24.
Docket Numbers: ER24–3065–001.
Applicants: Prairie Center Energy LLC.

Description: Tariff Amendment: Amendment to Market-Based Rate Application to be effective 10/28/2024.
Filed Date: 9/19/24.

Accession Number: 20240919–5193.
Comment Date: 5 p.m. ET 10/10/24.
Docket Numbers: ER24–3085–000.
Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Amendment to ISA No. 6154; Queue No. AE1–185 to be effective 11/20/2024.
Filed Date: 9/20/24.

Accession Number: 20240920–5062.
Comment Date: 5 p.m. ET 10/11/24.
Docket Numbers: ER24–3086–000.
Applicants: Southern California Edison Company.

Description: 205(d) Rate Filing: Second Amended LGIA Gaskell West TOT727 to be effective 9/21/2024.
Filed Date: 9/20/24.

Accession Number: 20240920–5079.
Comment Date: 5 p.m. ET 10/11/24.
Docket Numbers: ER24–3087–000.
Applicants: Pacific Gas and Electric Company.

Description: 205(d) Rate Filing: Amendment to WAPA TEA (RS 231) to be effective 1/1/2025.

Filed Date: 9/20/24.
Accession Number: 20240920–5081.
Comment Date: 5 p.m. ET 10/11/24.
Docket Numbers: ER24–3088–000.
Applicants: Public Service Company of New Mexico.

Description: 205(d) Rate Filing: Revised Transmission Construction and Interconnection Agreement with GridLiance to be effective 8/21/2024.
Filed Date: 9/20/24.

Accession Number: 20240920–5098.
Comment Date: 5 p.m. ET 10/11/24.
Docket Numbers: ER24–3089–000.
Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Original WMPA Service No. 7373; AG1–558 to be effective 8/23/2024.

Filed Date: 9/20/24.
Accession Number: 20240920–5146.
Comment Date: 5 p.m. ET 10/11/24.

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

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful

public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: September 20, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-22088 Filed 9-25-24; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-12233-01-OA]

Science Advisory Board Scientific and Technological Achievement Awards Panel; Closed Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a meeting of the Scientific and Technological Achievement Awards (STAA) Panel. The purpose of the meeting is to review nominations and make recommendations for the Early Career Science and Technology Award. The meeting is closed to the public.

DATES: The SAB STAA Panel will meet on the following dates. All times listed are in eastern time.

1. November 4, 2024, from 10:30 a.m. to 4 p.m.
2. November 6, 2024, from 10:30 a.m. to 3 p.m.
3. November 13, 2024, from 10:30 a.m. to 3 p.m.

ADDRESSES: The SAB STAA Panel meeting will be conducted virtually.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain further information concerning this notice may contact Dr. Shaunta Hill-Hammond, Designated Federal Officer (DFO), via telephone (202) 564-3343, or via email at hill-hammond.shaunta@epa.gov. General information about the SAB as well as any updates concerning the meeting announced in this notice can be found on the SAB website at <https://sab.epa.gov>.

SUPPLEMENTARY INFORMATION:

Background: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the EPA Administrator on the scientific and technical basis for agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C. 10. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the SAB STAA Panel, will hold a closed meeting to review nominations for the Early Career Science and Technology Award and make recommendations for award recipients.

The Early Career Science and Technology Award at EPA, established in 2024, recognizes early-career professionals who have made distinguished contributions to scientific research or technology development to EPA and show exceptional promise of continued achievements throughout their EPA career. All technical staff (*e.g.*, mathematicians, engineers, social/physical/biological/computational scientists, physicians, and others) are eligible for this annual award. Recipient(s) receive a one-time monetary stipend of \$10,000 and a commemorative plaque.

The SAB reviews the STAA nomination packages according to the following three evaluation factors:

- **Scientific achievements:** How has the nominee led, conducted, or influenced scientific research that significantly advanced a field of research (to include the integration and synthesis of data) or developed technology within the employee's scientific or technical area of expertise, such that the product of their work had a substantial impact on the mission of ORD and EPA.

- **Impact:** How have the efforts of the nominee resulted in improved customer, partner, or stakeholder satisfaction through documented accolades, recognition, or direct influence on decisions or actions and consistently demonstrated the highest level of accountability in achieving the organization's, ORD's and the Agency's goals and mission.

- **Partnership:** How have efforts of the nominee led or initiated significant collaborations successfully influencing the organization, workgroup, or teams in activities or projects that result in improvements in program policies,

processes, or other key activities (commensurate with career stage).

I have determined that the meetings of the STAA Panel and Chartered SAB will be closed to the public because they are concerned with selecting employees deserving of awards. In making these recommendations, the Agency requires full and frank advice from the SAB. This advice will involve professional judgments on the relative merits of various employees and their respective work. Such matters relate solely to EPA's internal personnel rules and practices and involve the discussion of information that is of a personal nature and the disclosure of which would be a clearly unwarranted invasion of personal privacy and, therefore, are protected from disclosure by section 10(d) of the Federal Advisory Committee Act (FACA), 5 U.S.C. Code 10, and subsections (c)(2) and (c)(6) of the Government in the Sunshine Act, 5 U.S.C. 552b. Minutes of the meetings of the STAA Panel and the Chartered SAB will be kept and certified by the chair of those meetings.

Meeting cancellation: The November 6, 2024 and November 13, 2024 meeting dates may be cancelled if the STAA Panel concludes its deliberative discussions early.

Michael S. Regan,
Administrator.

[FR Doc. 2024-22032 Filed 9-25-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0476; FRL-11109-03-OCSPJP]

Tris(2-chloroethyl) Phosphate (TCEP); Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing the availability of the final risk evaluation under the Toxic Substances Control Act (TSCA) for tris(2-chloroethyl) phosphate (TCEP). The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the

conditions of use. The Agency used the best available science to prepare this final risk evaluation and determined, based on the weight of scientific evidence, that TCEP poses unreasonable risk to human health and the environment. Under TSCA, EPA must initiate risk management actions to address the unreasonable risk.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0476, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information: Chloe O'Haire, Existing Chemical Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–6785; email address: ohaire.chloe@epa.gov.

For general information: The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of particular interest to those involved in the manufacture (defined under TSCA section 3(9) to include import), processing, distribution, use, and disposal of TCEP, related industry trade organizations, non-governmental organizations with an interest in human and environmental health, state and local governments, Tribal Nations, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. As such, the Agency has not attempted to describe all the specific entities that this action might apply to. If you need help determining applicability, consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

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

The Agency conducted this risk evaluation under TSCA section 6, 15 U.S.C. 2605, which requires that EPA conduct risk evaluations on chemical substances and identifies the minimum components the Agency must include in all chemical substance risk evaluations. Each risk evaluation must be conducted

consistent with the best available science, be based on the weight of scientific evidence, and consider reasonably available information, pursuant to 15 U.S.C. 2625(h), (i), and (k). See also the implementing procedural regulations at 40 CFR part 702.

C. What action is the Agency taking?

EPA is announcing the availability of the final risk evaluation under TSCA for TCEP. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use. EPA has used the best available science to prepare this final risk evaluation and based on the weight of scientific evidence, determined that TCEP poses unreasonable risk to human health and the environment. Upon a determination of unreasonable risk, EPA must initiate risk management action as required pursuant to 15 U.S.C 2605(a) to address the unreasonable risk.

II. Background

A. What is tris(2-chloroethyl) phosphate (TCEP)?

TCEP is a chlorinated phosphate ester present as a transparent liquid that is imported, processed, distributed, used, and disposed of as part of industrial, commercial, and consumer conditions of use. TCEP is primarily used as an additive flame retardant and plasticizer in polymers used in aerospace equipment and products, and as an additive flame retardant in paint and coating manufacturing. In the past, TCEP was processed in many products made in the United States, including fabrics and textiles, some types of foam, and construction materials—some of which may still be in use today. The total aggregate annual production volume reported for TCEP under the Chemical Data Reporting (CDR) rule ranged from 39,682 to 158,728 pounds between 2012 and 2015, with no CDR-qualifying reports after 2015; annual production volume of TCEP is now somewhere below the 2020 CDR reporting threshold of 25,000 pounds, with Datamyne showing 593 pounds of TCEP imported in 2020.

B. Risk Evaluation of Tris(2-chloroethyl) Phosphate (TCEP)

In 2019, EPA announced its designation of TCEP as a high priority

substance for risk evaluation under TSCA (Ref. 1). A draft scope of the TCEP risk evaluation was issued in April 2020 (Ref. 2), and after receiving public comment, EPA announced the final scope of the TCEP risk evaluation in September 2020 (Ref. 3). In June 2023, EPA proposed a significant new use rule (SNUR) for TCEP (Ref. 4). In December 2023, EPA released a draft risk evaluation for public comment and peer review (Ref. 5), and issued a request for nominations of expert reviewers to conduct a letter peer review was issued in September 2023 (Ref. 6).

The final risk evaluation of TCEP addresses comments from both the public and letter peer review periods. The responses to peer review and public comments, along with the final TCEP risk evaluation (Ref. 7) and a non-technical summary (Ref. 8), are available in the docket.

For more information about the TSCA risk evaluation process for existing chemicals, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

III. Unreasonable Risk Determination

EPA has determined that TCEP presents an unreasonable risk of injury to human health and the environment under the conditions of use. EPA has determined that the unreasonable risk to human health presented by TCEP is due to: (1) Non-cancer effects and cancer in workers from dermal and inhalation exposures; (2) Non-cancer effects and cancer in consumers from ingestion, dermal, and inhalation exposures; and (3) Non-cancer effects and cancer in the general population, including subsistence and tribal fishers from fish consumption.

Additionally, EPA has determined that TCEP presents unreasonable risk to the environment due to chronic effects (mortality) to aquatic species using empirical fish data. Ten conditions of use from importing, processing, industrial uses, commercial uses, and consumer uses were identified to significantly contribute to the unreasonable risk.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory actions to the extent necessary so that TCEP no longer presents an unreasonable risk. The Agency expects to focus its risk management action on the conditions of use that significantly contribute to the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to contribute significantly to unreasonable risk and

may select from among a suite of risk management requirements in TSCA section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) contributing significantly to unreasonable risk, even if the upstream activities do not contribute significantly to the unreasonable risk.

IV. References

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

1. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. **Federal Register**. 84 FR 71924, December 30, 2019 (FRL-10003-15).
2. EPA. Draft Scopes of the Risk Evaluations To Be Conducted for Thirteen Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. **Federal Register**. 85 FR 19941, April 9, 2020 (FRL-10007-11).
3. EPA. Final Scopes of the Risk Evaluations To Be Conducted for Twenty Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. **Federal Register**. 85 FR 55281, September 2020 (FRL-10013-90).
4. EPA. Flame Retardants; Significant New Uses Rules for Certain Non-Ongoing Uses. **Federal Register**. Docket ID No. EPA-HQ-OPPT-2023-0012. **Federal Register**. 88 FR 40728, June 22, 2023 (FRL-9430-01-OCSP).
5. EPA. Tris(2-chloroethyl) Phosphate (TCEP); Draft Risk Evaluation Under the Toxic Substances Control Act (TSCA); Letter Peer Review; Notice of Availability, Public Meeting and Request for Comment. **Federal Register**. 88 FR 86894, December 15, 2023 (FRL-11109-02-OCSP).
6. EPA. Tris(2-chloroethyl) Phosphate (TCEP); Draft Risk Evaluation under the Toxic Substances Control Act (TSCA); Letter Peer Review; Request for Nominations of Expert Reviewers. **Federal Register**. 88 FR 67278, September 29, 2023 (FRL-11109-01-OCSP).

7. EPA. Tris(2-chloroethyl) phosphate (TCEP); Regulation Under the Toxic Substances Control Act (TSCA); Comment Summary and Responses. September 2024. EPA Document ID No. EPA-740-R-24-011.
8. EPA. Non-technical Summary of the TSCA Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP). September 2024. EPA Document ID No. EPA-740-S-24-003.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: September 23, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024-22061 Filed 9-25-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-12281-01-OEJECR: EPA-HQ-OEJECR-2024-0147]

White House Environmental Justice Advisory Council; Notification of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification for a public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the U.S. Environmental Protection Agency (EPA) hereby provides notice that the White House Environmental Justice Advisory Council (WHEJAC) will meet on the dates and times described below. Due to unforeseen administrative circumstances, EPA is announcing this meeting with less than 15 calendar days public notice. This meeting is open to the public. For additional information about registering to attend the meeting or provide public comment, please see "REGISTRATION" under **SUPPLEMENTARY INFORMATION**. Pre-registration is required.

DATES: The WHEJAC will convene an in-person public meeting with a virtual option on Wednesday, October 9, 2024, from approximately 9:00 a.m. to 8:00 p.m. Central Time. Meeting discussions will focus on several topics including, but not limited to, workgroup activities, panel discussions, updates from the White House Council on Environmental Quality (CEQ) and other federal agencies, and new formal charges for the WHEJAC. The WHEJAC invites public comments at the meeting on the subjects listed below (see **SUPPLEMENTARY INFORMATION**). Members of the public who wish to participate in the public comment period must register by 11:59 p.m. Eastern Time, Friday, October 4, 2024.

ADDRESSES: The WHEJAC meeting will be held at The Jackson Center, 6001 Moquin Drive Northwest in Huntsville, Alabama 35806.

FOR FURTHER INFORMATION CONTACT: Audrie Washington, WHEJAC Designated Federal Officer, U.S. EPA; email: whejac@epa.gov; telephone: (202) 441-7295. For additional information about the WHEJAC, visit <https://www.epa.gov/environmentaljustice/white-house-environmental-justice-advisory-council#meetings>.

SUPPLEMENTARY INFORMATION: The Charter of the WHEJAC (available at <https://www.epa.gov/system/files/documents/2024-05/whejac-amended-charter-jan-5-2024.pdf>) states that the advisory committee "will provide independent advice and recommendations to the Chair of the Council on Environmental Quality (CEQ) and to the White House Environmental Justice Interagency Council (IAC) on how to increase the federal government's efforts to address current and historic environmental injustice. The WHEJAC will provide advice and recommendations about broad cross-cutting issues related, but not limited, to issues of environmental justice and pollution reduction, energy, climate change mitigation and resiliency, environmental health, and racial inequity. The WHEJAC's efforts will include a broad range of strategic, scientific, technological, regulatory, community engagement, and economic issues related to environmental justice."

Registration: Individual registration is required for the public meeting. Information on how to register is located at <https://www.epa.gov/environmentaljustice/white-house-environmental-justice-advisory-council>. Registration for the meeting is available until the scheduled end time of the meeting. Registration to speak during the public comment period will close at 11:59 p.m., Central Time, Friday, October 4, 2024. When registering, please provide your name, organization, city and state, and email address for follow up. Please also indicate whether you would like to provide public comment during the meeting, or if you are submitting written comments.

A. Public Comment: The WHEJAC is interested in receiving public comments relevant to the following charges and topics:

(1) *EJ.gov (or EnvironmentalJustice.gov)*: What features, functions, and information should be added to the site, and how could the site be improved over time to meet the needs of stakeholders and the public?

(2) *National Science and Technology Council (NSTC) Environmental Justice Science, Data, and Research Plan*: What metrics or indicators would prove most useful in evaluating whether the recommendations in the current Research Plan have been meaningfully integrated and used to support the advancement of environmental justice; what types of feedback mechanisms could be implemented to meaningfully capture community responses and integrate them into the planning of the NSTC Environmental Justice Subcommittee; what key areas should receive increased or decreased attention in the next iteration of the plan; and what innovative approaches or emerging technologies, should the Subcommittee consider in future Research Plans?

(3) *Place-Based and Community-Focused Initiatives*: What models of community-focused, multiagency collaboration have worked effectively; what methods, processes, principles, or other components have made these models effective in strengthening health or environmental protection or reducing environmental injustice affecting a specific local community or region; and in what ways could multiagency efforts at the federal level incorporate effective partnership or input from state, territorial, and local governments, consultation with Tribal governments, and engagement with communities with environmental justice concerns, community organizations, businesses, and members of the public?

(4) *The Environmental Justice Scorecard*: How has the public used Phase One and Phase Two of the Environmental Justice Scorecard, and how can the federal government improve future versions of the Environmental Justice Scorecard to continue to promote transparency and accountability to the public?

(5) *Justice40 Initiative*: How can the Federal government improve access to and awareness of Justice40 Initiative covered programs for entities eligible to apply for funding from those programs?

More information on WHEJAC Workgroup charges is located online at: <https://www.epa.gov/environmentaljustice/white-house-environmental-justice-advisory-council>, under WHEJAC Membership, Workgroups, and Charges.

Individuals or groups making remarks during the oral public comment period will be limited to three (3) minutes. EPA will give priority to speak during the meeting to public commenters with comments relevant to the topics and questions listed above. The WHEJAC will make every effort to hear from each public commenter who has registered to

provide oral comments during the time specified on the agenda but, in the interest of time, commenters are strongly encouraged to consider submitting written comments for the record. You can submit your written comments by using the webform at <https://www.epa.gov/environmental-justice/forms/white-house-environmental-justice-advisory-council-whejac-public-comment>; by emailing comments to whejac@epa.gov; or by visiting <http://www.regulations.gov> and opening Docket ID No. EPA-HQ-OEJECR-2024-0147. The WHEJAC will accept written comments through Wednesday, October 23, 2024.

B. Information About Services for Individuals with Disabilities or Requiring English Language Translation Assistance: For information about access or services for individuals requiring assistance, contact Audrie Washington at whejac@epa.gov. To request special accommodations for a disability or other assistance, please submit your request at least seven (7) working days prior to the meeting to give EPA sufficient time to process your request.

Deeohn Ferris,

Director, Office of Policy, Partnerships and Program Development (OPPPD) Office of Environmental Justice and External Civil Rights.

[FR Doc. 2024-21986 Filed 9-25-24; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-1228; FR ID 247230]

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 November 25, 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: 3060-1228.
Title: Connect America Fund—High Cost Portal Filing.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions.

Number of Respondents and Responses: 2,015 unique respondents; 4,590 responses.

Estimated Time per Response: 8 hours–60 hours.

Frequency of Response: On occasion, quarterly reporting requirements, annual reporting requirements, and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 410, and 1302.

Total Annual Burden: 86,263 hours.

Total Annual Cost: No Cost.

Needs and Uses: Through several orders, the Federal Communications Commission (the Commission) has recently changed or modified reporting obligations for high-cost support. Pursuant to the following orders, this

collection includes location reporting and related certification requirements of high-cost support recipients: *Connect America Fund et al.*, Report and Order, Order and Order on Reconsideration, and Further Notice of Proposed Rulemaking, 31 FCC Rcd 3087 (2016) (*2016 Rate-of-Return Order*); *Connect America Fund et al.*, Report and Order and Further Notice of Proposed Rulemaking, 31 FCC Rcd 5949 (2016) (*Phase II Auction Order*); *Connect America Fund et al.*, Order, 31 FCC Rcd 12086 (2016) (*ACS Phase II Order*); *Connect America Fund et al.*, Report and Order and Notice of Proposed Rulemaking, 29 FCC Rcd 876 (2014) (*Rural Broadband Experiments Order*); *Connect America Fund et al.*, Report and Order, 29 FCC Rcd 15644 (2014) (*Price Cap Order*); *Technology Transitions et al.*, Order *et al.*, 29 FCC Rcd 1433 (2014) (*Tech Transitions Order*); *Connect America Fund et al.*, Report and Order and Further Notice of Proposed Rulemaking, 31 FCC Rcd 10139 (2016) (*Alaska Plan Order*); *Connect America Fund et al.*, Order, 32 FCC Rcd 968 (2017) (*New York Auction Order*); *Connect America Fund et al.*, Report and Order, Further Notice of Proposed Rulemaking, and Order on Reconsideration, 33 FCC Rcd 11–893 (2018) (*2018 Rate-of-Return Order*); *The Uniendo a Puerto Rico and the Connect USVI Fund et al.*, Report and Order and Order on Reconsideration, 34 FCC Rcd 9109 (2019) (*PR-USVI Stage 2 Order*); *Rural Digital Opportunity Fund et al.*, Report and Order, 35 FCC Rcd 686 (2020) (*2020 Rural Digital Opportunity Fund Order*); *Enhanced A–CAM Report and Order*, FCC 23–60; *Connect America Fund et al.*, WC Docket No. 10–90 *et al.* WT Docket No. 10–208, Notice of Proposed Rulemaking and Report and Order, FCC 23–87 (Oct. 20, 2023) (*Administrative Order*).

This information collection addresses the requirement that certain carriers with high-cost reporting obligations file information about the locations to which they have deployed broadband service meeting applicable public interest requirements (location information). The HUBB, a web-based portal, is used to accept this information. The Commission and the Universal Service Administrative Company (USAC) will use this information to monitor the deployment progress of reporting carriers, to verify the reporting carriers' claims of service at the reported locations, and to conform broadband deployment data between the HUBB and BDC. Such activities help the Commission ensure that support is being used as intended.

In addition, because data filed in the HUBB is publicly accessible, the reporting helps ensure public accountability and transparency.

This information collection further addresses the Commission's efforts to develop and establish a uniform national dataset of locations where broadband could be deployed and upon which new coverage data could be overlaid using a single methodology to harmonize fixed broadband reporting nationwide with granular location data as part of the BDC and required by the Broadband Deployment Accuracy and Technology Availability Act, Public Law 116–130, 134 Stat. 228 (2020) (Broadband DATA Act). In furtherance of its obligations, the Commission established the Broadband Serviceable Location Fabric (Fabric), which consists of a single, nationwide fabric that will contain geocoded information for all locations where a broadband connection can be installed in the United States and territories (Broadband Serviceable Location or BSL). Each BSL contained in the Fabric is provided a unique identification number. The HUBB portal will be updated in order to have support recipients include the unique Fabric identification number when reporting or revising high-cost broadband deployment location data. Including the BSL Fabric Identification Number in HUBB reporting will improve the accuracy and reliability of the broadband data used to monitor progress and ensure accountability with Commission programs. All BSL Fabric Identification Numbers are associated with the latitude, longitude, address, and number of units at the location. Accordingly, reporting the BSL Fabric Identification Number associated with a location encompasses the latitude, longitude, address, and number of units at the location.

This information collection addresses the location reporting and related certification requirements of high-cost support recipients electing to receive support through the Enhanced A–CAM program, *see generally Enhanced A–CAM Order*, and other programs. On October 30, 2023, the Wireline Competition Bureau (WCB) authorized 368 rate-of-return carriers to receive Enhanced A–CAM support in various states. Of this number, 100 electing carriers had been receiving cost-based CAF BLS support in 118 unique study areas, and 216 electing carriers had been receiving model-based support (A–CAM). The interim and final deployment milestones required for the Enhanced A–CAM program will supersede the existing interim and final deployment milestones for the carriers

participating in eligible programs. However, Enhanced A–CAM carriers were required to still report in the HUBB their deployments for calendar year 2023 prior to the start of the support term for Enhanced A–CAM program (January 1, 2024) to ensure carriers continue in good faith to deploy broadband pursuant to existing commitments.

Carriers receiving high-cost support to serve locations are subject to specific public interest obligations related to speed, usage, latency, and price as well as certain deployment milestones. Specifically, the Commission imposed defined deployment obligations and associated HUBB reporting requirements (annual location reporting and build-out certifications) for all fixed support recipients as well as annual reporting and certification requirements for Uniendo a Puerto Rico Fund and Connect USVI Fund Stage 2 mobile support recipients.

We therefore propose to revise this information collection. Finally, we propose to modify the burdens associated with existing and new reporting requirements to account for additional carriers that will be subject to these requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–22098 Filed 9–25–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0166; FR ID 247327]

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 (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.

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.

DATES: Written PRA comments should be submitted on or before November 25, 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.

OMB Control Number: 3060-0166.

Title: Part 42, Section 42.6, Preservation of Records of Communications Common Carriers.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 49 respondents; 49 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in Section 220 of the Communications Act of 1934, as amended, 47 U.S.C. 220.

Total Annual Burden: 98 hours.

Total Annual Cost: No cost.

Needs and Uses: Section 42.6 requires a carrier to retain for eighteen months to assist the Department of Justice in its law enforcement activities telephone toll records that provide the billing information about telephone toll calls: the name, address, and telephone number of the caller, telephone number called, date, time and call length.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024-22097 Filed 9-25-24; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Open Meeting of the FDIC Systemic Resolution Advisory Committee

AGENCY: Federal Deposit Insurance Corporation.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Systemic Resolution Advisory Committee. The Advisory Committee will provide advice and recommendations on a broad range of policy issues regarding the resolution of systemically important financial companies. The meeting is open to the public. The public's means to observe this meeting of the FDIC Systemic Resolution Advisory Committee will be both in-person and via a Webcast live on the internet. In addition, the meeting will be recorded and subsequently made available on-demand approximately two weeks after the event. To view the live event, visit <http://fdic.windrosemedia.com>.

DATES: Tuesday, October 15, 2024, from 9:00 a.m. to 4:00 p.m.

ADDRESSES: The meeting will be held in the FDIC Cafeteria on the seventh floor of the FDIC Building located at 550 17th Street NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Ms. Debra A. Decker, Committee Management Officer of the FDIC, at (202) 898-8748.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of a range of issues and developments related to the resolution of systemically important financial companies. The agenda may be subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present a valid photo identification to enter the building. Observers requiring auxiliary aids (e.g., sign language interpretation) for this meeting should email DisabilityProgram@fdic.gov to

make necessary arrangements. This meeting of the FDIC Systemic Resolution Advisory Committee will also be Webcast live via the internet <http://fdic.windrosemedia.com>. For optimal viewing, a high-speed internet connection is recommended. To view the recording, visit <http://fdic.windrosemedia.com/index.php?category=Systemic+Resolution+Advisory+Committee>. Written statements may be filed with the Advisory Committee before or after the meeting.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 23, 2024.

James Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024-22085 Filed 9-25-24; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than October 11, 2024.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414. Comments can also be sent electronically to Comments.applications@chi.frb.org:

1. *Gregory S. Jeffers, Urbana, Illinois; and Tod A. Jeffers, Natalie A. Jeffers, Kathryn G. Jeffers, Joseph T. Jeffers, and Karen A. Jeffers, all of Bethany, Illinois;* as members of the Jeffers Family Group, a group acting in concert, to retain voting shares of Scott Bancshares, Inc., and thereby indirectly retain voting shares of Scott State Bank, both of Bethany, Illinois.

B. Federal Reserve Bank of Minneapolis (Mark Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to MA@mpls.frb.org:

1. *Barrett Doss, Los Angeles, California;* to join the Skalicky Family Group, a group acting in concert, to acquire voting shares of Stearns Financial Services, Inc., Saint Cloud, Minnesota, and thereby indirectly acquire voting shares of Stearns Bank National Association, Saint Cloud, Minnesota, and Stearns Bank of Upsala, National Association, Upsala, Minnesota.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2024–22107 Filed 9–25–24; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–24HP]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Compliance Attestation Statement for the Framework for Nucleic Acid Synthesis Screening” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on July 24, 2024 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy

of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Compliance Attestation Statement for the Framework for Nucleic Acid Synthesis Screening—New—Office of Science (OS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this Attestation Form is to assist providers of synthetic nucleic acids (Providers) and manufacturers of benchtop nucleic acid synthesis equipment (Manufacturers) in making an attestation that they are performing due diligence in screening product orders and customers consistent with the expectations outlined in the federal Framework for Nucleic Acid Synthesis Screening (Framework). While Providers and Manufacturers may choose a different mode to make such an attestation, this Attestation Form serves as a valid template. This statement of attestation will provide the U.S. Federal Government and researchers using any United States Government life sciences research award (e.g., research grant, contract, etc.) for procurement of synthetic nucleic acids or benchtop nucleic acid synthesis equipment reasonable assurance that Providers and Manufacturers are complying with the Framework.

CDC requests OMB approval for an estimated 20 annual burden hours. There are no costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Providers and manufacturers of synthetic nucleic acids and bench top nucleic acid synthesis equipment.	Annual Provider and Manufacturer Self-Attestation Statement.	60	1	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.

[FR Doc. 2024-21981 Filed 9-25-24; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-2744]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare &
Medicaid Services, Health and Human
Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by November 25, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT:
William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-2744—End Stage Renal Disease
Annual Facility Survey Form

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Annual Facility Survey Form; *Use:* The Program Management and Medical Information System (PMMIS) collects provider-specific and aggregate patient population data on ESRD beneficiaries treated by dialysis and transplant providers. Each facility

certification/survey record represents one provider. The CMS-2744 captures certification and other information about ESRD facilities approved by Medicare to provide kidney dialysis and transplant services. Additionally, the CMS-2744 captures activities performed during the calendar year, as well as aggregate year-end population counts for both Medicare beneficiaries and non-Medicare patients. The data elements include basic provider information such as provider certification and type of ownership; aggregated dialysis patient data such as the number of patients, number of deaths, and number of patients receiving different types of dialysis; dialysis treatment data; kidney transplant data such as number of transplants, type of transplants, and number of patients awaiting transplants; and the total number of each method used to obtain kidneys for transplants. The CMS-2744 collects data on hemodialysis patients dialyzing, vocational rehabilitation, and staffing. The accuracy of the Facility Survey depends on complete reporting by each facility.

Modifications to the CMS-2744 are (a) collection of days the dialysis facility is open; (b) shifts dialysis is provided; (c) adding "failed" to "return after transplant" for clarity; (d) removing questions related to vocational rehabilitation; and (e) aligning instructions with revisions. *Form Number:* CMS-2744 (OMB control number: 0938-0447); *Frequency:* Yearly; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 7,726; *Total Annual Responses:* 7,726; *Total Annual Hours:* 15,452. (For policy questions regarding this collection contact Christina Goatee at 410-786-6689.)

William N. Parham, III,

Director, Division of Information Collections
and Regulatory Impacts, Office of Strategic
Operations and Regulatory Affairs.

[FR Doc. 2024-21978 Filed 9-25-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10856]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare &
Medicaid Services, Health and Human
Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 28, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section

3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Managed Care and Supporting Regulations; *Use:* The collection of information request pertains to the attestation collection requirement at 42 CFR 438.6(c)(2)(ii)(H), which requires that providers receiving payment under a State directed payment attest that they do not participate in any hold harmless arrangement for any health care-related tax as specified in § 433.68(f)(3) in which the State or other unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the taxpayer harmless for all or any portion of the tax amount, and ensure either that (upon CMS request) such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations. *Form Number:* CMS-10856 (OMB control number: 0938-1453); *Frequency:* Yearly and once; *Affected Public:* Private sector and State, Local, or Tribal Governments; *Number of Respondents:* 1,088,094; *Total Annual Responses:* 1,088,138; *Total Annual Hours:* 145,523. (For questions regarding this collection contact Abigail Walker at 410-786-1725.)

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-21982 Filed 9-25-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Community Living****Announcing the Intent To Award a Single-Source Supplement for the Alternatives to Guardianship Youth Resource Center Cooperative Agreement**

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the University of Massachusetts for the Alternatives to Guardianship Youth Resource Center cooperative agreement. The purpose of this project is to divert high school students with intellectual and developmental disabilities (I/DD) away from guardianship to less restrictive decisional supports. The target audience for this information includes youth with I/DD, families and caregivers of high school students with I/DD, teachers, education administrators, advocates, vocational rehabilitation counselors, guidance counselors, and school district officials. The administrative supplement for FY 2024 will amount to \$200,000, bringing the total award for FY 2024 to \$500,000.

FOR FURTHER INFORMATION CONTACT: Dana Fink, 202-795-7604, dana.fink@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: This supplementary funding will expand the Alternatives to Guardianship Youth Resource Center's engagement and education efforts around diverting high school students with I/DD away from guardianship to less restrictive decisional supports. As a result of funding this Center, ACL expects that:

- More students with I/DD will have more decisional options, such as Powers of Attorney, supported-decision-making, joint bank accounts, bill paying services, and medical or educational release forms, on completion of high school;
- Fewer young adults with I/DD will be subject to guardianship;
- The public will become more knowledgeable of alternatives to guardianship; and
- Youth will become more independent by gaining job experience and personal responsibilities.

This supplement will fund:

- Support to enhance the engagement of youth advisory board members, including (1) a dedicated staff member for facilitation and administrative

coordination and support and; (2) paid opportunities for youth advisory board members to be more deeply engaged in project activities.

- Continued support for two additional staff members from grant partner Self-Advocates Becoming Empowered who have joined the youth ambassador training team.
- Support for travel for youth ambassadors and youth advisors to participate in conference presentations.
- Supervisory support for the youth trainer position that will begin. This youth trainer joined the Youth Ambassador workgroup and is a part of the training team that facilitates the third cohort of youth ambassadors from Texas, California, and New York.
- Continued enhancement to the project website, which includes a dedicated page for each of the 40+ youth ambassadors, youth-friendly products and videos, and plain language documents.

The administrative supplement for FY 2024 will amount to \$200,000, bringing the total award for FY 2024 to \$500,000.

Program Name: Center for Youth Voice Youth Choice (CYVYC) Alternatives to Guardianship Youth Resource Center.

Recipient: University of Massachusetts, Boston.

Period of Performance: The supplement award will be issued during the fifth year of the five-year project period of September 1, 2024, through August 31, 2025.

Total Supplement Award Amount: \$200,000.

Award Type: Cooperative Agreement.

Statutory Authority: 42 U.S.C. 15081(2).

Basis for award: The University of Massachusetts is currently funded to carry out the CYVYC Project for the period of September 1, 2020 through August 31, 2025. Much work has already been completed and further tasks are currently being accomplished. It would be unnecessarily time consuming and disruptive to the CYVYC project and the beneficiaries being served for ACL to establish a new grantee at this time when critical services are presently being provided in an efficient manner.

Dated: September 22, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024-22035 Filed 9-25-24; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Submission for OMB Review; Public Comment Request; ACL Administration on Aging Formula Grant Programs (OMB Control Number 0985–New)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to the proposed new information collection requirements relating to the ACL Administration on Aging Formula Grant Programs (OMB Control Number 0985–New).

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by October 28, 2024.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find the information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attention: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT:

Adam Mosey, ACL Administration on Aging, phone: 202–795–7631 and email: Adam.Mosey@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. This announcement solicits comments on the ACL Administration on Aging Formula Grant Programs. As a center in the Administration for Community Living, the Administration on Aging (AoA) provides expertise on program development, advocacy, initiatives for older Americans, their caregivers, and families. Working with state agencies, local agencies, grantees, and community

providers, AoA directs programs authorized by the Older Americans Act (OAA) of 1965 as amended (42 U.S.C. 3001 *et seq.*). The OAA provides the foundation for the National Aging Network, which includes ACL/AoA, state units on aging (SUA), area agencies on aging (AAA), Tribal organizations, service providers, and volunteers. SUAs are an integral part of the network responsible for developing and administering a multi-year state plan that advocates and aids older residents, their families, caregivers, and adults with disabilities. The Elder Justice Act (42 U.S.C. 1397j), passed in 2010 is the first comprehensive legislation to address the abuse, neglect, and exploitation of older adults at the federal level. The law authorized a variety of programs and initiatives to better coordinate federal responses to elder abuse, promote elder justice research and innovation, support Adult Protective Services (APS) systems, and provide additional protections for residents of long-term care facilities. The importance of these services at the state-level and local-level is demonstrated by the fact that states significantly leverage OAA funds to obtain other funding for these activities.

Through these programs, multi-year state plans, assurances, and other financial forms are needed to provide approval and oversight of grant recipients. ACL is seeking approval for a new information collection which will collect data related to AoA formula grant programs. This information collection will include data collection activity for state plans on aging and assurances, financial forms, and a corrective action plan (CAP) template each associated with aging formula grant management. The purpose of this information collection is for programmatic and financial management of the aging and APS formula grants. The state plan on aging documents and provides the opportunity report achievements and planned activities for the multi-year plan period. A wide range of constituents use or will use the state plans on aging to coordinate, monitor, evaluate, and improve aging network by using the state plans on aging as a blueprint for service planning and delivery. Additionally, ACL leverages state plans on aging to understand the numerous services older adults use, and to utilize the information for advocating the needs of older adults, and for requesting additional funding. The financial forms will assist in the facilitation of OAA formula grant management.

Financial forms provide statutorily required information regarding each state’s contribution to programs to ensure compliance with legislative requirements, pertinent federal regulations, and other applicable instructions and guidelines issued by ACL. This information will be used for federal oversight of the aging programs. OAA and APS grantees are required to comply with all terms and conditions contained in notices of award (NOA) issued by ACL.

When it is determined that a grantee is not in compliance with one or more of these requirements, ACL may require a grantee submit a plan to enter compliance under a CAP. Any such CAP may require ACL’s prior written approval, as determined by ACL. The CAP process is intended to be collaborative. Under a CAP, a grantee and ACL will jointly identify progress milestones and a feasible timeline for the grantee to come into compliance with the applicable requirement. Grantees must make a good faith effort

at achieving full compliance to continue with permission from ACL to operate under a CAP.

Comments in Response to the 60-Day Federal Register Notice

In accordance with 5 CFR 1320.8(d), ACL published a 60-day notice in the **Federal Register** on Wednesday, October 18, 2023, at 88 FR 71869 with a comment period that closed on December 18, 2023. ACL received one comment. The comment and ACL response is provided below:

Organization	Section	Comment	Response
Commonwealth of Virginia, Department for Aging and Rehabilitative Services.	Estimated Annualized Burden Table.	Noted that the burden estimates for State Plans on Aging, and State Plans on APS are too low. Recommended identification of ways to reduce reporting requirements, as well as revising burden estimates. Recommended survey of states to inform future burden estimates.	ACL appreciates the comment but declines to make changes at this time.

This 30-day notice publication makes correction to the information collection type in the previous 30-day notice published in the **Federal Register** on Tuesday, May 28, 2024, at 89 FR 46123. That notice requested public comment

on this information collection as a generic information collection request.

Estimated Program Burden

This new information collection incorporates ACL AoA formula grant programs previously approved under OMB control numbers: 0985–0004 and

0985–0009 and adds new state plans on aging and assurances, financial forms, and a corrective action plan (CAP) template, each associated with aging formula grant management.

ACL estimates the burden of this collection of information as follows:

Data collection activity	Form	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Unit on Aging (SUA)	State Plan on Aging	15	1	80	1,200
State Unit on Aging (SUA)	Financial Forms	56	5	1	280
OAA or APS Grantee	Corrective Action Plan	75	1	8	600
Total Estimated Burden	2,056

Dated: September 21, 2024.

Alison Barkoff,
Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–22034 Filed 9–25–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Submission for OMB Review; Public Comment Request; ACL Consolidated Program Performance Report (OMB Control Number 0985–New)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section

506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to the proposed new information collection relating to the ACL Consolidated Program Performance Report (OMB Control Number 0985–New).

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by October 28, 2024.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find the information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. By mail to the Office of Information and Regulatory

Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attention: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Shannon Skowronski, ACL Office of Performance and Evaluation, phone: 202-795-7438 and email: evaluation@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. This announcement solicits comments on the ACL Consolidated Program Performance Report, a mechanism to collect program performance reports for programs authorized by the Older Americans Act (Pub. L. 89-27 of 1965, as amended through Pub. L. 116-131 of 2020). The purpose of this new information collection request (ICR), is to collect program performance data for ACL formula and competitive grant programs authorized by the Older Americans Act (OAA), as required by and in accordance with Public Law 116-131 and 42 U.S.C. chapter 7, subchapter XX, division B (authorizing legislation); 45 CFR 75.342 (monitoring and reporting program performance); 45 CFR 75.301 (performance measurement); and the GPRA Modernization Act of 2010 (Pub. L. 111-352, sec. 12). ACL is primarily a grant-making agency whose mission is to maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers by supporting partnerships and providing funding, guidance, training, and technical assistance. The collection of program performance data is required for all ACL grantees, including grants authorized by the OAA, to:

1. Monitor achievement of program performance objectives,
2. Identify areas of performance that may benefit from technical assistance and/or corrective action,
3. Establish program policy and direction, and
4. Prepare responses and reports for Congress, the Office of Management and Budget (OMB), the public, and legislatively required reports.

If ACL did not collect program performance data, the agency would be unable to monitor and manage program performance as expected or develop program changes or improvements directed toward assuring the most effective use of limited OAA funds. ACL consistently looks for ways to streamline the collection of required program performance data. The proposed ACL Consolidated Program Performance Report is an efficient mechanism for the collection of program performance data elements across OAA authorized programs, and ensures each programs' indicators, demographics, priorities, and objectives are being achieved. The collection of performance elements will enable ACL to analyze program performance broadly across its grantee portfolio, allowing ACL and its grantees to align measures over time.

This new ICR will gather program performance data for OAA authorized grant programs under one consolidated report replacing OMB control numbers under the Performance (Progress) Report for AoA Grantees (0985-0006) and the State Performance Report for FY 2022-2025 (0985-0072).

Comments in Response to the 60-Day Federal Register Notice

A 60-day notice published in the **Federal Register** on December 5, 2023, at 88 FR 84335-84336. This 30-day

notice publication makes correction to the information collection type in the previous 30-day notice published in the **Federal Register** on March 25, 2024, at 89 FR 20663-20664. That notice requested public comment on this information collection as a generic ICR.

During the 60-day public comment period, ACL received two comments related to the *ACL Program Performance Report Template*. A summary of the comments and the ACL response is provided below:

Comment #1: Suggest including more specific instructions for completing the elements in the proposed *ACL Program Performance Report Template*:

ACL response: While ACL appreciates this suggestion, the instructions for completing the elements must be somewhat broad in order to account for differences in the goals, objectives, and activities across the programs.

Comment #2: Request confirmation that the grantee will be responsible for submitting a comprehensive program performance report each reporting period to ACL (as opposed to having grantees' subcontractors *each* submit individual reports to ACL).

ACL response: Although grantees could work with their subcontractors to gather information to complete their program performance report, grantees would be responsible for submitting a comprehensive program performance report for the specified reporting period.

Estimated Program Burden

ACL estimates the burden of this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Older Americans Act Title IV Grantee Performance Reports	1,189	2	10	23,780
Older Americans Act Title III and VII Grantee Performance Reports	56	1	70	3,920
Total Estimated Burden	27,700

Dated: September 21, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024-22036 Filed 9-25-24; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcing the Intent To Award a Single-Source Supplement for the Co-Occurring Resource Center for Individuals With I/DD

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the National Association of State Directors of Developmental Disabilities Services (NASDDDS) for the Co-Occurring Resource Center for Individuals with I/DD, called The Link Center. The

purpose of this project is to improve the quality of life for people with intellectual and/or developmental disabilities (I/DD), brain injuries, and co-occurring mental health conditions by supporting state agencies with policy development, service design, and service coordination resources, and sharing resources to individuals, families, direct support professionals, clinicians, and other policymakers. The administrative supplement for FY 2024 will amount to \$410,318 bringing the total award for FY 2024 to \$1,060,000.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Dana Fink, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Disabilities, (202) 795-7604 or via email dana.fink@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: This supplementary funding will expand the Co-Occurring Resource Center for Individuals with ID/DD (The Link Center)'s engagement and technical assistance efforts around supporting people with co-occurring I/DD, brain injuries, and co-occurring mental health conditions to live well in the community. Additionally, this supplement includes funding from SAMHSA through an interagency agreement to perform an environmental assessment of cross-system strategies to support children with I/DD, brain injuries, and other neurodevelopmental disabilities who also have complex behavioral health conditions. As a result of funding this center and the environmental assessment, ACL expects:

- Improved coordination between mental health, DD, Medicaid, and child welfare service systems to develop and/or amend policies and practices that fill service gaps, recruit and train competent staff, and assure equitable access to quality services.
- Increased number of mental health professionals and paraprofessionals, including community-based mobile crisis intervention service personnel, peer support workers, and service providers for the 988 Dialing Code for the National Suicide Prevention Lifeline, with the competencies needed to provide effective and culturally competent supports to individuals with co-occurring I/DD and mental health disabilities.
- Increased number of community service providers, who have the capacity to support children and adults with I/DD and co-occurring mental health disabilities.

- Improved awareness and knowledge of the strengths, needs, challenges, and systemic barriers experienced by children and adults with co-occurring I/DD and mental health disabilities.

- Improved ability to deliver responsive and equitable programming, training, and technical assistance.

- Increased self-determination, empowerment, and quality of life for people with co-occurring I/DD and mental health disabilities.

- Enhanced service delivery infrastructure, including mechanisms for ongoing and sustained engagement of individuals with lived experience.

This supplement will fund:

- Enhanced efforts related to children and families, including development of relationships with key national child welfare organizations.

- 10 focus groups of cross-system leaders in 10 states on system gaps resulting in adverse impacts on children with complex behavioral health needs.

- An in-person summit with federal and state officials and subject matter experts to discuss findings from the environmental assessment of promising practices and gaps related to children with complex behavioral health needs.

- Increased staff time for coordination, resource development, and accessibility efforts.

- Increased contributions from brain injury partners to align with that of other key partners more closely and better reflect the need to serve people with brain injury as well as I/DD.

- Resource development including paid participation of experts with lived experience to assist in development.

- Additional accessibility and language translation services.

Program Name: Co-Occurring Resource Center for Individuals with I/DD (The Link Center).

Recipient: The National Association of State Directors of Developmental Disabilities Services.

Period of Performance: The supplement award will be issued for the third year of the five-year project period of September 1, 2024, through August 31, 2025.

Total Supplement Award Amount: \$410,318.

Award Type: Cooperative Agreement.

Statutory Authority: This program is authorized under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 Public Law 106-402, Section 161(2) (B), (C) and (D) (42 U.S.C. 15081(2)).

Basis for Award: The National Association of State Directors of Developmental Disabilities Services is currently funded to carry out this

cooperative agreement for the period of September 1, 2022, through August 31, 2027. Much work has already been completed and further tasks are currently being accomplished. It would be unnecessarily time consuming and disruptive to the Link Center project and the beneficiaries being served for ACL to establish a new grantee at this time when critical services are presently being provided in an efficient manner.

Dated: September 21, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024-22037 Filed 9-25-24; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2024-E-0434, FDA-2024-E-0436, and FDA-2024-E-0437]

Determination of Regulatory Review Period for Purposes of Patent Extension; OGSIVEO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for OGSIVEO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by November 25, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 25, 2025. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of November 25, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket Nos. FDA-2024-E-0434, FDA-2024-E-0436, and FDA-2024-E-0437 for "Determination of Regulatory Review Period for Purposes of Patent Extension; OGSIVEO." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to

regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, OGSIVEO (nirogestat hydrobromide) indicated for adult patients with progressing desmoid tumors who require systemic treatment. Subsequent to this approval, the USPTO received patent term restoration applications for OGSIVEO (U.S. Patent Nos. 7,342,118; 7,795,447; and 7,951,958) from SpringWorks Therapeutics Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 17, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OGSIVEO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OGSIVEO is 5,425 days. Of this time, 5,089 days occurred during the testing phase of the regulatory review period, while 336 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* January 21, 2009. FDA has verified the applicant's

claim that the date the investigational new drug application became effective was on January 21, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 27, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for OGSIVEO (NDA 217677) was initially submitted on December 27, 2022.

3. *The date the application was approved:* November 27, 2023. FDA has verified the applicant's claim that NDA 217677 was approved on November 27, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,826 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22105 Filed 9–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Awards Unsolicited Proposal; Catalog of Federal Domestic Assistance (CFDA) Number: 93.079

AGENCY: Office of Population Affairs (OPA) and Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice of award of an unsolicited request for funding to be awarded as a single project through a grant to Stanford University, Palo Alto, CA.

SUMMARY: OPA announces the award of a single-source grant in response to an unsolicited proposal from Stanford University, Palo Alto, CA. The proposal submitted was not solicited either formally or informally by any federal government official. The grant award is administered by OPA in collaboration with the Centers for Disease Control and Prevention's Division of Adolescent and School Health (CDC DASH).

DATES: September 13, 2024.

FOR FURTHER INFORMATION CONTACT: Amy Margolis, Deputy Director, Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services at amy.margolis@hhs.gov or by telephone at 240–453–2820.

SUPPLEMENTARY INFORMATION:

Recipient: Stanford University, Palo Alto, CA.

Purpose of the Award: The purpose of this award is to conduct and disseminate policy research aligned with the eight goals of HHS's *Take Action for Adolescent Health and Well-being* to understand the impact of national, state, and local policies on meeting adolescents' needs, and to inform efforts towards strengthening commitments to funding, delivery of services, and meaningful youth engagement.

Amount of Award: \$999,855 annually for up to five years.

Project Period: The project period for the award will not exceed five years.

The goals of this project are to conduct and disseminate policy research aligned with *Take Action for Adolescents* to understand the impact of national, state, and local policies on access, availability, and quality of health care and health education for adolescents. Specifically, the project will (1) engage key stakeholders involved in *Take Action for Adolescence*, (2) conduct policy research to identify the impact of national, state, and local policies on access, availability, and quality of

health care and health education for adolescents, (3) develop a series of policy briefs that summarize the research and identify strategies to improve adolescent health services and support *Take Action for Adolescents*, and (4) disseminate the policy briefs and effective strategies through publications and focused events with key stakeholders to support sustainability engagements and actions plans to improve adolescent health and well-being. This project will help improve understanding of the impact of national, state, and local policy on education and services for adolescents, and ultimately on their health and well-being.

OPA performed an objective review of the unsolicited proposal from Stanford University with subject matter assistance from within the Department of Health and Human Services and internal proposal assessments. Based on this review, OPA determined that the proposal has merit.

Stanford University, under the leadership of Jonathan Klein, has the unique breadth of expertise in the field of adolescent health and the established partnerships with leading adolescent health organizations necessary for success of this project. Issuing a single-source award to Stanford University for this project will advance our collective understanding of the impact of national, state, and local policies on meeting adolescents' needs and will identify strategies for advancing *Take Action for Adolescents* and improving adolescent health and wellbeing.

This award is being made non-competitively because there is no current, pending, or planned funding opportunity announcement under which this proposal could compete.

Legislative Authority: Funding for this award is provided by CDC DASH with authority under section 301(a) of the Public Health Service Act, 42 U.S.C. 241(a). The grant award will be administered by OPA under an interagency agreement.

Dated: September 17, 2024.

Sarah Rosenthal,

Deputy Assistant Secretary for Population Affairs, Office of Population Affairs, Office of the Assistant Secretary for Health.

[FR Doc. 2024–22029 Filed 9–25–24; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Announcement of the Scientific Report Meeting of the 2025 Dietary Guidelines Advisory Committee**

AGENCY: Food, Nutrition, and Consumer Services (FNCS), U.S. Department of Agriculture (USDA); Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS).

ACTION: Notice; announcement of public meetings.

SUMMARY: The Departments of Health and Human Services and Agriculture announce the Scientific Report meeting of the 2025 Dietary Guidelines Advisory Committee (Committee). This meeting will be open to the public virtually. The period of written public comments to the Committee will remain open through Wednesday, October 7, 2024.

DATES:

The meetings and comment collection dates are scheduled as follows:

- The Scientific Report meeting will be held on October 21, 2024, from 11 a.m. to 6 p.m. eastern time and on October 22, 2024, from 11 a.m. to 6 p.m. eastern time. Registration is required for the livestream and opens to the public on October 1, 2024, at DietaryGuidelines.gov.

- The period for written public comments which opened on January 19, 2023, will close at 11:59 p.m. ET on Monday, October 7, 2024.

ADDRESSES: The meeting will be accessible online via livestream and recorded for later viewing. Registrants will receive the livestream information before the meeting.

FOR FURTHER INFORMATION CONTACT:

Designated Federal Officer, 2025 Dietary Guidelines Advisory Committee, Janet M. de Jesus, MS, RD; Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Phone: 240-453-8266; Email DietaryGuidelines@hhs.gov. Additional information is at DietaryGuidelines.gov.

SUPPLEMENTARY INFORMATION:

Authority and Purpose: Under Section 301 of Public Law 101-445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, title III), the Secretaries of HHS and USDA are directed to publish the *Dietary Guidelines for Americans* jointly at least every five years. See 88 FR 3423, January 19, 2023, for notice of the first meeting of the 2025 Dietary Guidelines Advisory Committee, the complete Authority and Purpose, and the

Committee's Task. The 2025 Dietary Guidelines Advisory Committee is formed and governed under the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. app).

Purpose of the Meeting: During the Scientific Report meeting, the Committee will review and discuss the scientific findings and advice included in its Scientific Report. Each subcommittee and working group will review and share their advice for Committee discussion. Following this meeting, the Committee will finalize and submit its Scientific Report to HHS and USDA.

Meeting Agendas: The agenda will be announced in advance of the meeting on DietaryGuidelines.gov.

Meeting Registration: This Committee meeting is open to the public. The meeting will be accessible online via livestream and recorded for later viewing. Registration is required for the livestream. To register, go to DietaryGuidelines.gov and click on the link for "Meeting Registration."

Meeting materials for each day of the meeting will be accessible after the respective meeting at DietaryGuidelines.gov. Materials may be requested by email at DietaryGuidelines@hhs.gov.

Public Comments: A call for written public comment to the Committee opened on January 19, 2023, and will remain open until 11:59 p.m. ET on Monday, October 7, 2024. This allows time for the Committee to review the comments before their final public meeting. Written comments may be submitted at Regulations.gov (Document ID: HHS-OASH-2022-0021-0001).

Paul Reed,

Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

[FR Doc. 2024-22048 Filed 9-25-24; 8:45 am]

BILLING CODE 4150-32-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Clinical Center; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors of the NIH Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion,

and evaluation of individual intramural programs and projects conducted by the Clinical Center, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: October 28, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate personnel qualifications, performance, and competence of individual investigators.

Place: Clinical Center, 10 Center Drive, Bethesda, MD 20892 (Virtual).

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: October 29, 2024.

Time: 10:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate personnel qualifications, performance, and competence of individual investigators.

Place: Clinical Center, 10 Center Drive, Bethesda, MD 20892 (Virtual).

Contact Person: Ronald Neumann, MD, Deputy Scientific Director, Clinical Center, National Institutes of Health, 10 Center Drive, Bethesda, MD 20892, 301-496-6455, rneumann@cc.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Dated: September 20, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-21989 Filed 9-25-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard**

[Docket No. USCG-2024-0389]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625-0077

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, 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: 1625–0077, Security Plans for Ports, Vessels, Facilities, and Outer Continental Shelf Facilities and Other Security-Related Requirements; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before October 28, 2024.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2024–0389]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to <https://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.

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, fax 202–372–8405, or email hqs-dg-m-cg-61-pii@uscg.mil 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. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2024–0389, and must be received by October 28, 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. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive. 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. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the <https://www.reginfo.gov>, comment-submission web page. OIRA posts its decisions on ICRs online at <https://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0077.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (89 FR 59747, July 23, 2024) required by 44 U.S.C. 3506(c)(2). In

response to that notice, we received one supportive comment. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Security Plans for Ports, Vessels, Facilities, and Outer Continental Shelf Facilities and Other Security-Related Requirements.

OMB Control Number: 1625–0077.

Summary: This information collection is associated with the maritime security requirements mandated by the Maritime Transportation Security Act of 2002 (MTSA). Security assessments, security plans, and other security-related requirements are in Title 33 CFR parts 101 through 106.

Need: This information is needed to determine if vessels and facilities are in compliance with certain security standards.

Forms: • CG–6025, Facility Vulnerability and Security Measures Summary.

Respondents: Vessel and facility owners and operators.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 1,070,430 hours to 747,075 hours a year, due to the USCG eliminating the Vulnerability and Security Measures Addendum (CG–6025A) from this collection and a decrease in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.*, chapter 35, as amended.

Dated: September 23, 2024.

Kathleen Claffie,
Chief, Office of Privacy Management, U.S.
Coast Guard.

[FR Doc. 2024–22094 Filed 9–25–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0138]

Agency Information Collection Activities; Revision; Biometric Identity

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in

accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than October 28, 2024) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Please submit written comments and/or suggestions in English. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (89 FR 20674) on March 25, 2024, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3)

suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions 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, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Biometric Identity.

OMB Number: 1651–0138.

Form Number: N/A.

Current Actions: Revision.

Type of Review: Revision.

Affected Public: Individuals.

Abstract: In order to enhance national security, the Department of Homeland Security is developing a biometric based entry and exit system capable of improving the information resources available to immigration and border management decision-makers. These biometrics may include: digital fingerprint scans, facial images, iris images or other biometrics. Biometrics may be collected from travelers entering or exiting the United States, including the collection of biometrics from vehicles upon entry. CBP continues to test and evaluate different technological and operational changes to improve the accuracy and speed of biometric collection.

The federal statutes that mandate DHS to create a biometric entry and exit system include: Section 2(a) of the Immigration and Naturalization Service Data Management Improvement Act of 2000 (DMIA), Public Law 106–215, 114 Stat. 337 (2000); section 205 of the Visa Waiver Permanent Program Act of 2000, Public Law 106–396, 114 Stat. 1637, 1641 (2000); section 414 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), Public Law 107–56, 115 Stat. 272, 353 (2001); section 302 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Border Security Act), Public Law 107–173, 116 Stat. 543, 552, (2002); section 7208 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), Public Law 108–458, 118 Stat. 3638, 3817 (2004); section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007, Public Law 110–53, 121 Stat. 266 (2007), Consolidated Appropriations Act, 2016,

Public Law 114–113, 129 Stat. 2242, 2493 (2016), section 110 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Public Law 104–208, 110 Stat. 3009–546 (1997), section 802 of the Trade Facilitation and Trade Enforcement Act of 2015, Public Law 114–125, 130 Stat. 122, 199 (2015), and sections 214, 215(a), 235(a), 262(a), 263(a) and 264(c) of the Immigration and Nationality Act of 1952, as amended, 8 U.S.C. 1184, 1185(a), 1225(a), 1302(a)(1303(a), 1304(c) and 1365b.

New Change: This revision submission will increase the number of respondents whose biometrics are collected in vehicles, and to seek an exemption from PRA citation requirements on biometric/privacy signage. CBP ports of entry and external partners such as airports and seaports post biometric entry-exit privacy signage at those locations where facial comparison technology is in use by or on behalf of CBP. Due to operation costs to main signage to be compliant with PRA requirements, CBP requests that in lieu of placing the OMB number’s expiration date on the privacy signage, CBP will link/reference the OMB number, expiration date, and PRA language on CBP’s biometric website: www.cbp.gov/travel/biometrics. In lieu of displaying the PRA language on the signage, it will be listed on the website along with the current expiration date. This exception reduces the reprint cost to the U.S. government and the external stakeholders and allows the current privacy signage to remain 508 compliant and PBRB approved.

Type of Information Collection: Biometric Data, Fingerprint Modality.

Estimated Number of Respondents: 58,657,882.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 58,657,882.

Estimated Time per Response: .0097 hours.

Estimated Total Annual Burden Hours: 568,981.

Type of Information Collection: Facial/Iris Modality.

Estimated Number of Respondents: 54,542,118.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 54,542,118.

Estimated Time per Response: .0025 hours.

Estimated Total Annual Burden Hours: 136,355.

Type of Information Collection: Facial Scan/Vehicle Modality.

Estimated Number of Respondents:
2,000,000.

Estimated Number of Annual

Responses per Respondent: 1.

Estimated Number of Total Annual
Responses: 2,000,000.

Estimated Time per Response: 0.

Estimated Total Annual Burden
Hours: 0.

Dated: September 20, 2024.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis
Branch, U.S. Customs and Border Protection.

[FR Doc. 2024–21953 Filed 9–25–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2024–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency
Management Agency, Department of
Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases

the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at <https://msc.fema.gov>.

FOR FURTHER INFORMATION CONTACT: Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacibit@fema.dhs.gov; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65. The currently effective community

number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at <https://msc.fema.gov>.

(Catalog of Federal Domestic Assistance No. 97.022, “Flood Insurance.”)

Nicholas A. Shufro,

Assistant Administrator (Acting) for Risk
Management, Federal Emergency
Management Agency, Department of
Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Alabama: Madison (FEMA Docket No.: B–2445).	City of Madison (23–04–3026P).	The Honorable Paul Finley, Mayor, City of Madison, 100 Hughes Road, Madison, AL 35758.	City Hall, 100 Hughes Road, Madison, AL 35758.	Sept. 26, 2024	010308
Colorado: Arapahoe (FEMA Docket No.: B–2437).	City of Centennial (23–08–0194P).	The Honorable Stephanie Piko, Mayor, City of Centennial, 13133 East Arapahoe Road, Centennial, CO 80112.	Southeast Metro Stormwater Authority, 7437 South Fairplay Street, Centennial, CO 80112.	Sep. 6, 2024	080315
El Paso (FEMA Docket No.: B–2437).	City of Manitou Springs (23–08–0292P).	The Honorable John Graham, Mayor, City of Manitou Springs, 606 Manitou Avenue, Manitou Springs, CO 80829.	City Hall, 606 Manitou Avenue, Manitou Springs, CO 80829.	Aug. 28, 2024	080063
Connecticut: New Haven (FEMA Docket No.: B–2437).	City of Meriden (24–01–0126P).	The Honorable Kevin Scarpato, Mayor, City of Meriden, 142 East Main Street, Meriden, CT 06450.	Public Works Department, 142 East Main Street, Meriden, CT 06450.	Aug. 28, 2024	090081
Florida: Manatee (FEMA Docket No.: B–2445).	Unincorporated areas of Manatee County (24–04–0371P).	Charlie Bishop, Manatee County Administrator, 1112 Manatee Avenue West, Bradenton, FL 34205.	Manatee County Administration Building, 1112 Manatee Avenue West, Bradenton, FL 34205.	Sep. 9, 2024	120153
Orange (FEMA Docket No.: B–2437).	City of Orlando (24–04–0053P).	The Honorable Buddy Dyer, Mayor, City of Orlando, 400 South Orange Avenue, Orlando, FL 32801.	Public Works Department, Engineering Division, 400 South Orange Avenue, 8th Floor, Orlando, FL 32801.	Sep. 9, 2024	120186

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Orange (FEMA Docket No.: B-2437).	Unincorporated areas of Orange County (23-04-5522P).	The Honorable Jerry L. Demings, Mayor, Orange County, 201 South Rosalind Avenue, 5th Floor, Orlando, FL 32801.	Orange County Stormwater Management Division, 4200 South John Young Parkway, Orlando, FL 32839.	Aug. 30, 2024	120179
Pasco (FEMA Docket No.: B-2439).	Unincorporated areas of Pasco County (23-04-1143P).	Jack Mariano, Chair, Pasco County Board of Commissioners, 37918 Meridian Avenue, Dade City, FL 33525.	Pasco County Building Construction Services Department, 8731 Citizens Drive, Suite 230, New Port Richey, FL 34654.	Sep. 5, 2024	120230
Walton (FEMA Docket No.: B-2437).	City of Freeport (23-04-5559P).	The Honorable Russ Barley, Mayor, City of Freeport, 112 Highway 20 West, Freeport, FL 32439.	City Hall, 112 Highway 20 West, Freeport, FL 32439.	Sep. 5, 2024	120319
North Carolina:					
Durham (FEMA Docket No.: B-2445).	Unincorporated areas of Durham County (23-04-5200P).	Nida Allam, Chair, Durham County Board of Commissioners, 200 East Main Street, Durham, NC 27701.	Durham City-County Planning Department, 101 City Hall Plaza, Durham, NC 27701.	Sept. 3, 2024	370085
Durham (FEMA Docket No.: B-2437).	Unincorporated areas of Durham County (23-04-6337P).	Nida Allam, Chair, Durham County Board of Commissioners, 200 East Main Street, Durham, NC 27701.	Durham City-County Planning Department, 101 City Hall Plaza, Durham, NC 27701.	Sept. 5, 2024	370085
Pennsylvania: Philadelphia (FEMA Docket No.: B-2437).	City of Philadelphia (24-03-0065P).	The Honorable Cherelle L. Parker, Mayor, City of Philadelphia, 1 South Penn Square, Suite 215, Philadelphia, PA 19102.	Department of Licenses and Inspections, 1401 JFK Boulevard, Philadelphia, PA 19102.	Sep. 3, 2024	420757
Tennessee: Rutherford (FEMA Docket No.: B-2439).	City of Murfreesboro (24-04-2722P).	The Honorable Shane McFarland, Mayor, City of Murfreesboro, 111 West Vine Street, Murfreesboro, TN 37130.	City Hall, 111 West Vine Street, Murfreesboro, TN 37130.	Sep. 4, 2024	470168
Texas:					
Bexar (FEMA Docket No.: B-2439).	City of San Antonio (23-06-1913P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78214.	Sep. 9, 2024	480045
Bexar (FEMA Docket No.: B-2439).	City of San Antonio (23-06-2731P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78214.	Sep. 9, 2024	480045
Collin and Denton (FEMA Docket No.: B-2437).	City of Celina (23-06-2493P).	The Honorable Ryan Tubbs, Mayor, City of Celina, 142 North Ohio Street, Celina, TX 75009.	City Hall, 142 North Ohio Street, Celina, TX 75009.	Aug. 27, 2024	480133
Collin (FEMA Docket No.: B-2445).	City of Celina (23-06-2687P).	The Honorable Ryan Tubbs, Mayor, City of Celina, 142 North Ohio Street, Celina, TX 75009.	City Hall, 142 North Ohio Street, Celina, TX 75009.	Sep. 3, 2024	480133
Collin (FEMA Docket No.: B-2437).	Unincorporated areas of Collin County (23-06-2493P).	The Honorable Chris Hill, Collin County Judge, 2300 Bloomdale Road, McKinney, TX 75071.	Collin County Juvenile Justice Alternative Education Program Building, 4690 Community Avenue, Suite 200, McKinney, TX 75071.	Aug. 27, 2024	480130
Collin (FEMA Docket No.: B-2445).	Unincorporated areas of Collin County (23-06-2687P).	The Honorable Chris Hill, Collin County Judge, 2300 Bloomdale Road, McKinney, TX 75071.	Collin County Juvenile Justice Alternative Education Program Building, 4690 Community Avenue, McKinney, TX 75071.	Sep. 3, 2024	480130
Denton (FEMA Docket No.: B-2439).	City of Denton (23-06-0359P).	Sara Hensley, City of Denton Manager, 215 East McKinney Street, Denton, TX 76201.	Development Services Department, 401 North Elm Street, Denton, TX 76201.	Sep. 9, 2024	480194
Denton (FEMA Docket No.: B-2439).	Unincorporated areas of Denton County (23-06-0359P).	The Honorable Andy Eads, Denton County Judge, 1 Courthouse Drive, Suite 3100, Denton, TX 76208.	Denton County Development Services Department, 3900 Morse Street, Denton, TX 76208.	Sep. 9, 2024	480774
Denton (FEMA Docket No.: B-2437).	Unincorporated areas of Denton County (23-06-2493P).	The Honorable Andy Eads, Denton County Judge, 1 Courthouse Drive, Suite 3100, Denton, TX 76208.	Denton County Development Services Department, 3900 Morse Street, Denton, TX 76208.	Aug. 27, 2024	480774
Johnson (FEMA Docket No.: B-2439).	City of Cleburne (23-06-0045P).	The Honorable Scott Cain, Mayor, City of Cleburne, P.O. Box 677, Cleburne, TX 76031.	City Hall, 10 North Robinson Street, Cleburne, TX 76033.	Aug. 30, 2024	485462
Smith (FEMA Docket No.: B-2437).	City of Tyler (23-06-2411P).	The Honorable Don Warren, Mayor, City of Tyler, P.O. Box 2039, Tyler, TX 75710.	Development Center, 423 West Ferguson Street, Tyler, TX 75702.	Sep. 3, 2024	480571
Tarrant (FEMA Docket No.: B-2439).	City of Crowley (23-06-2689P).	The Honorable Billy P. Davis, Mayor, City of Crowley, 201 East Main Street, Crowley, TX 76036.	Planning and Development Department, 201 East Main Street, Crowley, TX 76036.	Sep. 9, 2024	480591

[FR Doc. 2024-22065 Filed 9-25-24; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency****[Docket ID FEMA-2024-0002]****Final Flood Hazard Determinations****AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.**ACTION:** Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP).

DATES: The date of January 17, 2025 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at <https://msc.fema.gov> by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacibit@fema.dhs.gov; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these

changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at <https://msc.fema.gov>.

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Nicholas A. Shufro,
Assistant Administrator (Acting) for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Lee County, Alabama and Incorporated Areas Docket No.: FEMA-B-2319	
City of Auburn	Planning and Development, 171 North Ross Street, Auburn, AL 36830.
City of Opelika	Planning Department, 700 Fox Trail, Opelika, AL 36801.
Town of Notasulga	Town Hall, 76 West Main Street, Notasulga, AL 36866.
Unincorporated Areas of Lee County	Lee County Building Inspection, 100 Orr Avenue, Opelika, AL 36801.
Clay County, Illinois and Incorporated Areas Docket No.: FEMA-B-2360	
City of Flora	City Hall, 131 East 2nd Street, Flora, IL 62839.
Unincorporated Areas of Clay County	Clay County Courthouse, 111 East Chestnut Street, Room 106, Louisville, IL 62858.
Village of Clay City	Village Hall, 318 South Walnut Street SE, Clay City, IL 62824.
Village of Louisville	Village Hall, 177 South Main Street, Louisville, IL 62858.
Village of Sailor Springs	Village Hall, 107 South Washington Street, Sailor Springs, IL 62824.
Effingham County, Illinois and Incorporated Areas Docket No.: FEMA-B-2364	
City of Altamont	Municipal Building, 202 North 2nd Street, Altamont, IL 62411.
City of Effingham	City Hall, 201 East Jefferson Avenue, Effingham, IL 62401.
Unincorporated Areas of Effingham County	Effingham County Courthouse, 101 North 4th Street, Suite 304, Effingham, IL 62401.
Village of Dieterich	Village Hall, 103 West Section Street, Dieterich, IL 62424.
Village of Teutopolis	Village Hall, 106 West Main Street, Teutopolis, IL 62467.
Village of Watson	Village Hall, 104 North Monroe Street, Watson, IL 62473.
Holmes County, Mississippi and Incorporated Areas Docket No.: FEMA-B-2275	
City of Lexington	City Hall, 112 Spring Street, Lexington, MS 39095.
Unincorporated Areas of Holmes County	Holmes County Administrative Offices, 408 Court Square, Lexington, MS 39095.

Community	Community map repository address
Leflore County, Mississippi and Incorporated Areas Docket No.: FEMA-B-2275	
Unincorporated Areas of Leflore County	Leflore County Chancery Clerk's Office, 306 West Market Street, Greenwood, MS 38930.
Madison County, Mississippi and Incorporated Areas Docket No.: FEMA-B-1936, B-2035, B-2275	
City of Canton	City Hall, 226 East Peace Street, Canton, MS 39046.
City of Madison	City Hall, 1004 Madison Avenue, Madison, MS 39110.
City of Ridgeland	City Hall, 100 West School Street, Ridgeland, MS 39157.
Pearl River Valley Water Supply District	Pearl River Valley Water Supply District Building and Permit Department, 100 Reservoir Park Road, Brandon, MS 39047.
Unincorporated Areas of Madison County	Madison County Administrative Building, 125 West North Street, Canton, MS 39046.
Bertie County, North Carolina and Incorporated Areas Docket No.: FEMA-B-2303	
Town of Askewville	Bertie County Inspection Department, 106 Dundee Street, Windsor, NC 27983.
Town of Colerain	Town Hall, 101 Winton Street, Suite B, Colerain, NC 27924.
Town of Lewiston-Woodville	Town Hall, 103 West Church Street, Lewiston-Woodville, NC 27849.
Town of Windsor	Building Inspections Department, 128 South King Street, Windsor, NC 27983.
Unincorporated Areas of Bertie County	Bertie County Inspection Department, 106 Dundee Street, Windsor, NC 27983.
Jones County, North Carolina and Incorporated Areas Docket No.: FEMA-B-1718 and B-2077	
Unincorporated Areas of Jones County	Jones County Government Office Complex, 418 Highway 58 North, Trenton, NC 28585.
New Hanover County, North Carolina and Incorporated Areas Docket No.: FEMA-B-1523	
Unincorporated Areas of New Hanover County	New Hanover County Engineering Department, 230 Government Center Drive, Suite 160, Wilmington, NC 28403.
Onslow County, North Carolina and Incorporated Areas Docket No.: FEMA-B-1523 and B-1718	
Town of Holly Ridge	Town Hall, 212 North Dyson Street, Holly Ridge, NC 28445.
Town of North Topsail Beach	Town Hall, 2008 Loggerhead Court, North Topsail Beach, NC 28460.
Unincorporated Areas of Onslow County	Onslow County Floodplain Administration, 234 Northwest Corridor Boulevard, Jacksonville, NC 28540.
Pitt County, North Carolina and Incorporated Areas Docket No.: FEMA-B-2303	
Unincorporated Areas of Pitt County	Pitt County Office Building, 1717 West 5th Street, Greenville, NC 27834.
Hays County, Texas and Incorporated Areas Docket No.: FEMA-B-1757, B-2032, B-2330, and B-2275	
City of Buda	Engineering Department, 405 East Loop Street, Building 100, Buda, TX 78610.
City of Dripping Springs	Public Works Department, 511 Mercer Street, Dripping Springs, TX 78620.
City of Kyle	Building Department, 100 West Center Street, Kyle, TX 78640.
City of San Marcos	Engineering Department, City Hall, 630 East Hopkins Street, San Marcos, TX 78666.
City of Wimberley	Planning and Development, 221 Stillwater Road, Wimberley, TX 78676.
City of Woodcreek	City Hall, 41 Champions Circle, Woodcreek, TX 78676.
Unincorporated Areas of Hays County	Hays County Development Services Department, 2171 Yarrington Road, Suite 100, Kyle, TX 78640.
Village of Bear Creek	Village of Bear Creek Mayor's Office, 6705 Highway 290 West, Austin, TX 78753.

Community	Community map repository address
Monroe County, West Virginia and Incorporated Areas Docket No.: FEMA-B-2345	
Town of Alderson	City Hall, 311 South Monroe Street, Alderson, WV 24910.
Town of Peterstown	Town Hall, 229 Thomas Street, Peterstown, WV 24963.
Unincorporated Areas of Monroe County	Monroe County 911 Center, 39 Nota Street, Union, WV 24983.

[FR Doc. 2024-22067 Filed 9-25-24; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Docket ID FEMA-2024-0002; Internal Agency Docket No. FEMA-B-2462]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbabit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbabit@fema.dhs.gov; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Nicholas A. Shufro,

Assistant Administrator (Acting) for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
California:						
Los Angeles.	City of Los Angeles (24–09–0592P).	The Honorable Karen Bass, Mayor, City of Los Angeles, 200 North Spring Street, Los Angeles, CA 90012.	Department of Public Works, 1149 South Broadway, Suite 810, Los Angeles, CA 90015.	https://msc.fema.gov/portal/advanceSearch .	Dec. 27, 2024	060137
Los Angeles.	Unincorporated areas of Los Angeles County (24–09–0592P).	Lindsey Horvath, Chair, Los Angeles County Board of Supervisors, 500 West Temple Street, Room 821, Los Angeles, CA 90012.	Los Angeles County Watershed Management Department, 900 South Fremont Avenue, Alhambra, CA 91803.	https://msc.fema.gov/portal/advanceSearch .	Dec. 27, 2024	065043
Colorado:						
Arapahoe	City of Aurora (23–08–0489P).	The Honorable Mike Coffman, Mayor, City of Aurora, 15151 East Alameda Parkway, Aurora, CO 80012.	Public Works Department, 15151 East Alameda Parkway, Suite 3200, Aurora, CO 80012.	https://msc.fema.gov/portal/advanceSearch .	Dec. 20, 2024	080002
Arapahoe	Unincorporated areas of Arapahoe County (23–08–0489P).	Carrie Warren-Gully, Chair, Arapahoe County Board of Commissioners, 5334 South Prince Street, Littleton, CO 80120.	Arapahoe County Public Works and Development Department, 6924 South Lima Street, Centennial, CO 80112.	https://msc.fema.gov/portal/advanceSearch .	Dec. 20, 2024	080011
Jefferson ..	City of Lakewood (23–08–0727P).	The Honorable Wendi Strom, Mayor, City of Lakewood, 480 South Allison Parkway, Lakewood, CO 80226.	Public Works Department, 470 South Allison Parkway, Lakewood, CO 80226.	https://msc.fema.gov/portal/advanceSearch .	Dec. 20, 2024	085075
Jefferson ..	Unincorporated areas of Jefferson County (23–08–0417P).	Lesley Dahlkemper, Chair, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Suite 5550, Golden, CO 80419.	Jefferson County Planning and Zoning Division, 100 Jefferson County Parkway, Suite 3550, Golden, CO 80419.	https://msc.fema.gov/portal/advanceSearch .	Dec. 27, 2024	080087
Jefferson ..	Unincorporated areas of Jefferson County (23–08–0727P).	Lesley Dahlkemper, Chair, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Suite 5550, Golden, CO 80419.	Jefferson County Planning and Zoning Division, 100 Jefferson County Parkway, Suite 3550, Golden, CO 80419.	https://msc.fema.gov/portal/advanceSearch .	Dec. 20, 2024	080087
Florida:						
Bay	Unincorporated areas of Bay County (24–04–3454P).	Robert Majka, Manager, Bay County, 840 West 11th Street, Panama City, FL 32401.	Bay County Planning and Zoning Department, 840 West 11th Street, Panama City, FL 32401.	https://msc.fema.gov/portal/advanceSearch .	Jan. 2, 2025 ...	120004
Collier	Unincorporated areas of Collier County (24–04–1528P).	Chris Hall, Chair, Collier County Board of Commissioners, 3299 Tamiami Trail East, Suite 303, Naples, FL 34112.	Collier County Growth Management Community Development Department, 2800 North Horseshoe Drive, Naples, FL 34104.	https://msc.fema.gov/portal/advanceSearch .	Dec. 24, 2024	120067

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Monroe	Unincorporated areas of Monroe County (24–04–4132P).	The Honorable Holly Merrill Raschein, Mayor, Monroe County Board of Commissioners, 102050 Overseas Highway, Suite 234, Key Largo, FL 33037.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Key Largo, FL 35050.	https://msc.fema.gov/portal/advanceSearch .	Dec. 20, 2024	125129
Monroe	Village of Islamorada (24–04–4463P).	The Honorable Joseph Buddy Pinder III, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	https://msc.fema.gov/portal/advanceSearch .	Dec. 27, 2024	120424
Orange	City of Orlando (24–04–3768P).	The Honorable Buddy Dyer, Mayor, City of Orlando, 400 South Orange Avenue, Orlando, FL 32801.	Public Works Department Engineering Division, 400 South Orange Avenue, 8th Floor, Orlando, FL 32801.	https://msc.fema.gov/portal/advanceSearch .	Jan. 2, 2025 ...	120186
Palm Beach.	City of Delray Beach (23–04–6363P).	Terrence Moore, Manager, City of Delray Beach, 100 Northwest 1st Avenue, Delray Beach, FL 33444.	Building Inspections Department, 100 Northwest 1st Avenue, Delray Beach, FL 33444.	https://msc.fema.gov/portal/advanceSearch .	Dec. 9, 2024 ..	125102
Volusia	City of Daytona Beach (24–04–2270P).	The Honorable Derrick Henry, Mayor, City of Daytona Beach, 301 South Ridgewood Avenue, Daytona Beach, FL 32114.	City Hall, 301 South Ridgewood Avenue, Daytona Beach, FL 32114.	https://msc.fema.gov/portal/advanceSearch .	Dec. 13, 2024	125099
Illinois: DuPage	Village of Addison (24–05–0830P).	The Honorable Richard Veenstra, Mayor, Village of Addison, 1 Friendship Plaza, Addison, IL 60101.	Village Hall, 1 Friendship Plaza, Addison, IL 60101.	https://msc.fema.gov/portal/advanceSearch .	Dec. 27, 2024	170198
Indiana: Marion	City of Indianapolis (24–05–1185P).	The Honorable Joe Hogsett, Mayor, City of Indianapolis, 200 East Washington Street, Suite 2501, Indianapolis, IN 46204.	City Hall, 1200 Madison Ave., Suite 100, Indianapolis, IN 46225.	https://msc.fema.gov/portal/advanceSearch .	Dec. 27, 2024	180159
Marion	Town of Speedway (24–05–1185P).	Jason Delisle, President, Town of Speedway Council, 5300 Crawfordsville Road, Speedway, IN 46224.	Town Hall, 1450 North Lynhurst Drive, Speedway, IN 46224.	https://msc.fema.gov/portal/advanceSearch .	Dec. 27, 2024	180162
Iowa: Black Hawk.	City of Waterloo (22–07–1024P).	The Honorable Quentin Hart, Mayor, City of Waterloo, 715 Mulberry Street, Waterloo, IA 50703.	City Hall, 715 Mulberry Street, Waterloo, IA 50703.	https://msc.fema.gov/portal/advanceSearch .	Dec. 13, 2024	190025
Kansas: Johnson ...	City of Olathe (23–07–0361P).	The Honorable John Bacon, Mayor, City of Olathe, 100 East Santa Fe Street, Olathe, KS 66061.	City Hall, 100 East Santa Fe Street, Olathe, KS 66061.	https://msc.fema.gov/portal/advanceSearch .	Dec. 18, 2024	200173

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Johnson ...	Unincorporated areas of Johnson County (23–07–0361P).	Mike Kelly, Chair, Johnson County Board of Commissioners, 111 South Cherry Street, Suite 3300, Olathe, KS 66061.	Johnson County Communications Center, 11880 South Sunset Drive, Olathe, KS 66061.	https://msc.fema.gov/portal/advanceSearch .	Dec. 18, 2024	200159
Johnson ...	City of Overland Park (23–07–0829P).	The Honorable Curt Skoog, Mayor, City of Overland Park, 8500 Santa Fe Drive, Overland Park, KS 66212.	City Hall, 8500 Santa Fe Drive, Overland Park, KS 66212.	https://msc.fema.gov/portal/advanceSearch .	Dec. 18, 2024	200174
Michigan: Kalamazoo	City of Kalamazoo (24–05–1071P).	The Honorable David Anderson, Mayor, City of Kalamazoo, 241 West South Street, Kalamazoo, MI 49007.	City Hall, 241 West South Street, Kalamazoo, MI 49007.	https://msc.fema.gov/portal/advanceSearch .	Dec. 16, 2024	260315
Oakland ...	City of Rochester Hills (24–05–0583P).	The Honorable Bryan Barnett, Mayor, City of Rochester Hills, 1000 Rochester Hills Drive, Rochester Hills, MI 48309.	City Hall, 1000 Rochester Hills Drive, Rochester Hills, MI 48309.	https://msc.fema.gov/portal/advanceSearch .	Dec. 9, 2024 ..	260471
Minnesota: Cottonwood.	City of Windom (23–05–2934P).	The Honorable Dominic Jones, Mayor, City of Windom, P.O. Box 38, Windom, MN 56101.	City Hall, 444 9th Street, Windom, MN 56101.	https://msc.fema.gov/portal/advanceSearch .	Dec. 12, 2024	270090
Cottonwood.	Unincorporated areas of Cottonwood County (23–05–2934P).	Kelly Thongvivong, Cottonwood County Coordinator, 28606 County Road 1, Comfrey, MN 56019.	Cottonwood County Environmental Department, 339 9th Street, Windom, MN 56101.	https://msc.fema.gov/portal/advanceSearch .	Dec. 12, 2024	270622
Nevada: Washoe ...	City of Reno (24–09–0743P).	The Honorable Hillary Schieve, Mayor, City of Reno, 1 East 1st Street, Reno, NV 89505.	City Hall, 1 East 1st Street, Reno, NV 89505.	https://msc.fema.gov/portal/advanceSearch .	Dec. 27, 2024	320020
Washoe ...	Unincorporated areas of Washoe County (24–09–0743P).	Alexis Hill, Chair, Washoe County Board of Commissioners, 1001 East 9th Street, Reno, NV 89512.	Washoe County Administration Complex, 1001 East 9th Street, Reno, NV 89512.	https://msc.fema.gov/portal/advanceSearch .	Dec. 27, 2024	320019
New Jersey: Bergen	Borough of Ho-Ho-Kus (23–02–0548P).	The Honorable Thomas Randall, Mayor, Borough of Ho-Ho-Kus, 333 Warren Avenue, Ho-Ho-Kus, NJ 07423.	Borough Hall, 333 Warren Avenue, Ho-Ho-Kus, NJ 07423.	https://msc.fema.gov/portal/advanceSearch .	Dec. 9, 2024 ..	340044
Bergen	Village of Ridgewood (23–02–0548P).	The Honorable Paul Vagianos, Mayor, Village of Ridgewood, 131 North Maple Avenue, Ridgewood, NJ 07450.	Village Hall, 131 North Maple Avenue, Ridgewood, NJ 07450.	https://msc.fema.gov/portal/advanceSearch .	Dec. 9, 2024 ..	340067
North Carolina:						

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Cumberland.	Town of Hope Mills (24–04–0689P).	The Honorable Jessie Bellflowers, Mayor, Town of Hope Mills, 5770 Rockfish Road, Hope Mills, NC 28348.	Development and Planning Department, 5770 Rockfish Road, Hope Mills, NC 28348.	https://msc.fema.gov/portal/advanceSearch .	Nov. 20, 2024	370312
Cumberland.	Unincorporated areas of Cumberland County (24–04–0689P).	Glenn Adams, Chair, Cumberland County Board of Commissioners, P.O. Box 1829, Fayetteville, NC 28301.	Cumberland County Engineering and Infrastructure Department, 130 Gillespie Street, Suite 214, Fayetteville, NC 28301.	https://msc.fema.gov/portal/advanceSearch .	Nov. 20, 2024	370076
Texas: Denton	Town of Argyle (24–06–0767P).	The Honorable Rick Bradford, Mayor, Town of Argyle, P.O. Box 609, Argyle, TX 76226.	Town Hall, 308 Denton Street, Argyle, TX 76226.	https://msc.fema.gov/portal/advanceSearch .	Dec. 30, 2024	480775
Gillespie ...	City of Fredericksburg (24–06–1109P).	The Honorable Jeryl Hoover, Mayor, City of Fredericksburg, 126 West Main Street, Fredericksburg, TX 78624.	City Hall, 126 West Main Street, Fredericksburg, TX 78624.	https://msc.fema.gov/portal/advanceSearch .	Dec. 19, 2024	480252
Hidalgo	City of Edinburg (23–06–2507P).	The Honorable Ramiro Garza Jr., Mayor, City of Edinburg, 415 West University Drive, Edinburg, TX 78539.	Engineering Department, 415 West University Drive, Edinburg, TX 78539.	https://msc.fema.gov/portal/advanceSearch .	Dec. 9, 2024 ..	480338
Travis	City of Austin (23–06–1884P).	T.C. Broadnax, Manager, City of Austin, P.O. Box 1088, Austin, TX 78767.	City Hall, 301 West 2nd Street, Austin, TX 78701.	https://msc.fema.gov/portal/advanceSearch .	Dec. 23, 2024	480624

[FR Doc. 2024–22066 Filed 9–25–24; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service**

[FWS–R3–OSA–2024–N045;
FXSC142003MON30–245–FF03S00000; OMB
Control Number 1018–New]

**Agency Information Collection
Activities; Submission to the Office of
Management and Budget; Pollinator
Conservation Social Network Analysis
Survey**

AGENCY: Fish and Wildlife Service,
Interior.

ACTION: Notice of information collection;
request for comment.

SUMMARY: In accordance with the
Paperwork Reduction Act of 1995, we,
the U.S. Fish and Wildlife Service
(Service), are proposing a new
information collection.

DATES: Interested persons are invited to
submit comments on or before October
28, 2024.

ADDRESSES: Written comments and
recommendations for the proposed

information collection should be
submitted within 30 days of publication
of this notice at [https://
www.reginfo.gov/public/do/PRAMain](https://www.reginfo.gov/public/do/PRAMain).
Find this particular information
collection by selecting “Currently under
Review—Open for Public Comments” or
by using the search function. Please
provide a copy of your comments to the
Service Information Collection
Clearance Officer, U.S. Fish and
Wildlife Service, MS: PRB (JAO/3W),
5275 Leesburg Pike, Falls Church, VA
22041–3803 (mail); or by email to Info_Coll@fws.gov. Please reference “1018—
New Pollinator Survey” in the subject
line of your comments.

FOR FURTHER INFORMATION CONTACT: To
request additional information about
this information collection request
(ICR), contact Madonna L. Baucum,
Service Information Collection
Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703)
358–2503. Individuals in the United
States who are deaf, deafblind, hard of
hearing, or have a speech disability may
dial 711 (TTY, TDD, or TeleBraille) to
access telecommunications relay
services. Individuals outside the United
States should use the relay services

offered within their country to make
international calls to the point-of-
contact in the United States.

SUPPLEMENTARY INFORMATION: In
accordance with the Paperwork
Reduction Act (PRA, 44 U.S.C. 3501 *et
seq.*) and its implementing regulations
at 5 CFR 1320.8(d)(1), all information
collections require approval under the
PRA. We may not conduct or sponsor
and you are not required to respond to
a collection of information unless it
displays a currently valid OMB control
number.

On May 22, 2024, we published in the
Federal Register (89 FR 45006) a notice
of our intent to request that OMB
approve this information collection. In
that notice, we solicited comments for
60 days, ending on July 22, 2024. In an
effort to increase public awareness of,
and participation in, our public
commenting processes associated with
information collection requests, the
Service also published the **Federal
Register** notice on [Regulations.gov](https://www.regulations.gov)
(Docket FWS–R3–OSA–2024–0064) to
provide the public with an additional
method to submit comments (in
addition to the typical U.S. mail
submission method). We received two

comments in response to that notice which did not address the information collection requirements; therefore, no response is required.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. 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 can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Fish and Wildlife Act of 1956 (16 U.S.C. 742d) designates the Department of the Interior as a key agency responsible for the conservation and protection of wildlife and fisheries resources in the United States. This responsibility dictates that we gather accurate data on conservation efforts through means such as research to improve the development, management, and advancement of conservation efforts. At the June 2022 Monarch

Butterfly Summit, the Secretary of the Interior announced that the Service would establish a national Center for Pollinator Conservation (Center), funded through annual appropriations. Formally launched later that year, the Center serves as a science and collaboration hub across internal Service programs and regions as well as with external agencies and partners. The Center helps to direct conservation actions that can reverse declining pollinator population trends.

The Center is seeking to conduct a social network analysis to collect information regarding the structure and functions of pollinator networks throughout the United States, key influencers and network clusters, network gaps, and the diffusion of information across the broad pollinator conservation community. The proposed survey collects information necessary to support the Center's role as a science and collaboration hub helping inform evidence-based decisions to create, sustain, and strengthen relationships and communication channels across individuals and organizations to increase awareness of, collaboration on, and efficacy of pollinator conservation efforts.

In addition to an overview of the survey (Section 1), the proposed survey collects the following information:

- Respondent's organization and its involvement in pollinator conservation efforts (Section 2);
- Collaboration on pollinator conservation, including identification of collaborative organizations and collaboration types (Section 3);
- Network characteristics, including how organizations work together and potential barriers (Section 4);
- Respondent's role within their organization, along with name and email address (Section 5); and
- Additional comments on the survey or pollinator conservation in general (Section 6).

We will use the information collected in this effort to develop multiple products aimed at translating the data into information that can strengthen partnerships, identify gaps, and inform conservation decisions.

The public may request a copy of the draft survey instrument by sending a request to the Service Information Collection Clearance Officer (see **ADDRESSES**, above).

Title of Collection: Pollinator Conservation Social Network Analysis.
OMB Control Number: 1018–New.
Form Number: None.
Type of Review: New.

Respondents/Affected Public: Private sector and government respondents

(*e.g.*, Federal, State, Tribal, nongovernmental organizations (NGOs), academic entities, etc.) that work on pollinator conservation efforts throughout North America, with primary focus in the United States.

Total Estimated Number of Annual Respondents: 265 (160 private sector respondents, including academic entities and NGOs, and 205 State/Local/Tribal/Federal agencies/organizations).

Total Estimated Number of Annual Responses: 265.

Estimated Completion Time per Response: 20 minutes.

Total Estimated Number of Annual Burden Hours: 89.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: None.

Note: We estimate that approximately 100 U.S. Federal employees will respond to the survey (for a total estimate of 365 annual respondents); however, because U.S. Federal employees are exempt from the Paperwork Reduction Act, they are removed from the burden calculations.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2024–22043 Filed 9–25–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500181176]

Call for Nominations for the Alaska Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of call for nominations.

SUMMARY: The purpose of this notice is to request public nominations for the Bureau of Land Management's (BLM) Alaska Resource Advisory Council (RAC) to fill two existing vacancies. The RAC provides advice and recommendations to the BLM on land use planning and management of the National System of Public Lands within its geographic area.

DATES: All nominations must be received no later than October 28, 2024.

ADDRESSES: Nominations and completed applications should be sent to Azure

Hall, BLM Alaska State Office, 222 West 7th Avenue #13, Anchorage, AK 99513; phone: (907) 271-5960; email: ahall@blm.gov.

FOR FURTHER INFORMATION CONTACT:

Emma Roach, BLM Alaska Communications Director, BLM Alaska State Office, 222 West 7th Avenue #13, Anchorage, AK 99513; phone: (907) 271-5960; email: eroach@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Federal Land Policy and Management Act (FLPMA) directs the Secretary of the Interior to involve the public in planning and issues related to management of lands administered by the BLM. Section 309 of FLPMA (43 U.S.C. 1739) directs the Secretary to establish 10- to 15-member citizen-based advisory councils that are consistent with the Federal Advisory Committee Act. As required by the applicable regulations, RAC membership must be balanced and representative of the various interests concerned with the management of the public lands. The BLM regulations governing the operation of RACs are found at 43 CFR subpart 1784.

The BLM is seeking nominations for individuals in the following two categories:

Category Two—Representatives of nationally or regionally recognized environmental organizations; dispersed recreational activities; archaeological and historical interests; or nationally or regionally recognized wild horse and burro interest groups.

Category Three—Hold State, county, or local elected office; are employed by a State agency responsible for the management of natural resources, land, or water; represent Indian Tribes within or adjacent to the area for which the RAC is organized; are employed as academicians in natural resource management or the natural sciences; or represent the affected public-at-large.

Individuals may nominate themselves or others. Nominees must be residents of the State of Alaska. The BLM will evaluate nominees based on their education, training, experience, and knowledge of the geographic area of the RAC. Nominees should demonstrate a commitment to collaborative resource decision-making.

The following must accompany all nominations:

- A completed RAC application, which can either be obtained through your local BLM office or online at: https://www.blm.gov/sites/default/files/docs/2022-05/BLM-Form-1120-19_RAC-Application.pdf.
- Letters of reference from represented interests or organizations; and
- Any other information that addresses the nominee's qualifications.

Simultaneous with this notice, BLM Alaska will issue an online announcement providing additional information for submitting nominations.

(Authority: 43 CFR 1784.4-1)

Steven Cohn,

BLM Alaska State Director.

[FR Doc. 2024-21954 Filed 9-25-24; 8:45 am]

BILLING CODE 4331-10-P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[DOI-2024-0010; RR83550000, 245R5065C6, RX.59389832.1009676]

Privacy Act of 1974; System of Records

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Interior (DOI) is issuing a public notice of its intent to modify the Bureau of Reclamation (Reclamation) Privacy Act system of records, INTERIOR/WBR-31, Acreage Limitation. DOI is revising this notice to change the system number to be consistent with Reclamation's title, propose new and modified routine uses, and update all sections of the notice to accurately reflect management of the system of records. This modified system will be included in DOI's inventory of record systems.

DATES: This modified system will be effective upon publication. New or modified routine uses will be effective October 28, 2024. Submit comments on or before October 28, 2024.

ADDRESSES: You may send comments identified by docket number DOI-2024-0010 by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for sending comments.
- *Email:* DOI_Privacy@ios.doi.gov. Include docket number DOI-2024-0010 in the subject line of the message.

- *U.S. Mail or Hand-Delivery:* Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.

Instructions: All submissions received must include the agency name and docket number DOI-2024-0010. All comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Regina Magno, Associate Privacy Officer, Bureau of Reclamation, P.O. Box 25007, Denver, CO 80225, privacy@usbr.gov or (303) 445-3326.

SUPPLEMENTARY INFORMATION:

I. Background

Reclamation maintains the INTERIOR/WBR-31, Acreage Limitation, system of records. The purpose of this system is to obtain from landowners and lessees written information on their landholdings that is pertinent to their compliance with the ownership and full cost pricing provisions required by statute and regulations. The records are used by Reclamation to ensure contractually obligated irrigation districts and contract holders are following reporting and certification requirements of Federal reclamation law (Pub. L. 97-293).

DOI is publishing this revised notice to change the system number to reflect Reclamation's title; update the system manager and system location sections; expand on categories of individuals covered by the system, the categories of records and records source categories sections; update authorities for maintenance of the system; update the storage, safeguards, and records retention schedule; update the notification, records access and contesting procedures; reorganize the sections and provide general updates in accordance with the Privacy Act of 1974 and Office of Management and Budget (OMB) Circular A-108, *Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act*.

Additionally, Reclamation is changing the routine uses from a numeric to alphabetic list and is proposing to modify existing routine uses to provide clarity and transparency and reflect updates consistent with standard DOI routine uses. Routine use A was modified to further clarify disclosures to the Department of Justice or other

Federal agencies, when necessary, in relation to litigation or judicial proceedings. Routine use B has been modified to clarify disclosures to a congressional office to respond to or resolve an individual's request made to that office. Routine use D has been modified to allow Reclamation to refer matters to the appropriate Federal, State, local, or foreign agencies, or other public authority agencies responsible for investigating or prosecuting violations of, or for enforcing, or implementing, a statute, rule, regulation, order, or license. Routine use J was slightly modified to allow Reclamation to share information with appropriate Federal agencies or entities when reasonably necessary to prevent, minimize, or remedy the risk of harm to individuals or the Federal Government resulting from a breach in accordance with OMB Memorandum M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information*.

Reclamation is proposing to add new routine uses C, E, F, G, H, I, L, M, and N to facilitate sharing of information with agencies and organizations to ensure the efficient management of all land, facilities, and waterbodies under Reclamation's jurisdiction, promote the integrity of the records in the system, or carry out a statutory responsibility of Reclamation or the Federal Government. Proposed routine use C facilitates sharing of information with the Executive Office of the President to respond to an inquiry by the individual to whom that record pertains. Proposed routine use E allows Reclamation to share information with an official of another Federal agency to assist in the performance of their official duties related to reconciling or reconstructing an individual's record. Proposed routine use F facilitates sharing of information related to hiring, issuance of a security clearance, or a license, contract, grant, or benefit. Proposed routine use G allows Reclamation to share information with the National Archives and Records Administration to conduct records management inspections. Proposed routine use H allows Reclamation to share information with external entities, such as State, territorial and local governments and Tribal organizations needed in response to court orders and/or for discovery purposes related to litigation. Proposed routine use I allows Reclamation to share information with an expert, consultant, grantee, shared service provider, or contractor (including employees of the contractor) of DOI that performs services requiring access to these records on DOI's behalf

to carry out the purposes of the system. Proposed routine use L allows Reclamation to share information with OMB during the coordination and clearance process in connection with legislative affairs. Proposed routine use M allows Reclamation to share information with the Department of the Treasury to recover debts owed to the United States. Routine use N allows Reclamation to share information with the news media and the public, with approval by the Public Affairs Officer and Senior Agency Official for Privacy in consultation with counsel if there is a legitimate public interest in the disclosure of the information.

Pursuant to the Privacy Act, 5 U.S.C. 552a(b)(12), DOI may disclose information from this system to consumer reporting agencies as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)) to aid in the collection of outstanding debts owed to the Federal Government.

II. Privacy Act

The Privacy Act of 1974, as amended, embodies fair information practice principles in a statutory framework governing the means by which Federal agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to records about individuals that are maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act defines an individual as a United States citizen or lawful permanent resident. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DOI by complying with DOI Privacy Act regulations at 43 CFR part 2, subpart K, and following the procedures outlined in the Records Access, Contesting Record, and Notification Procedures sections of this notice.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the existence and character of each system of records that the agency maintains and the routine uses of each system. The INTERIOR/Reclamation-31, Acreage Limitation, system of records notice is published in its entirety below. In accordance with 5 U.S.C. 552a(r), DOI has provided a report of this system of records to OMB and to Congress.

III. Public Participation

You should be aware your entire comment including your personally identifiable information, such as your address, phone number, email address, or any other personal information in your comment, may be made publicly available at any time. While you may request to withhold your personally identifiable information from public review, we cannot guarantee we will be able to do so.

SYSTEM NAME AND NUMBER:

INTERIOR/Reclamation-31, Acreage Limitation.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Reclamation records in this system are maintained at:

(1) Bureau of Reclamation, Mission Assurance and Protection Organization, 6th and Kipling, Building 67, MS 84-55000 (RRA), Denver, CO 80225; and

(2) District offices in which subject individual submitted certification and reporting forms. District office addresses may be obtained from the Reclamation Law Administration Division of the Mission Assurance and Protection Organization.

SYSTEM MANAGER(S):

Manager, Mission Assurance and Protection Organization, Reclamation Law Administration Division, Bureau of Reclamation, P.O. Box 25007, MS 84-55000 (RRA), Denver, CO 80225.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Reclamation Act of 1902, (Pub. L. 57-161), as amended and supplemented; Public Law 97-293; Reclamation Reform Act of 1982, (43 U.S.C. 390aa, *et seq.*), as amended, at sections 206, 224(c), 224(g), and 228; Acreage Limitation Rules and Regulations, 43 CFR part 426; and Information Requirements for Certain Farm Operations in Excess of 950 Acres and the Eligibility of Certain Formerly Excess Land, 43 CFR part 428.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to obtain from landowners and lessees written information on their landholdings to administer the acreage limitation provisions of Federal reclamation law, and to ensure compliance with the statutory and regulatory requirements for the receipt of subsidized Reclamation irrigation water, including the ownership and full-cost pricing provisions of Federal reclamation law.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system include members of the public, individual landholders, individual land lessees, individual or entity farm operators, and officials of Federal and non-Federal entities. This system contains records concerning corporations and other business entities, which are not subject to the Privacy Act. However, records pertaining to individuals acting on behalf of corporations and other business entities may reflect personal information that may be maintained in this system of records.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records maintained on all individuals may include: Names, personal addresses, personal home telephone numbers, personal cell phone numbers, and information related to the administration of landholdings, acreage limitation, and irrigation subsidies.

Records on landholders and lessees may include: Employer Identification Numbers; citizenship status; status pursuant to Federal reclamation law; acreage owned and/or leased; legal descriptions or assessor parcel numbers; deeds; contracts or agreements relative to the transfer of land ownerships, including excess land sales and pertinent details of such sales; signature authorization documents; power-of-attorney documents; irrevocable elections; terms and effective dates of leases; leases; lease/purchase options; trust agreements; partnership agreements; and corporate resolutions.

Records on farm operators may include: Farm operating agreements, type of services provided, acreage operated by farm operators, and identification of part-owners of the farm operator.

RECORD SOURCE CATEGORIES:

Records in the system are obtained from water districts, contractors, individuals, legal entities, and Federal and non-Federal entities including State and local governmental units.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DOI as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys,

or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

- (1) DOI or any component of DOI;
- (2) Any other Federal agency appearing before the Office of Hearings and Appeals;
- (3) Any DOI employee or former employee acting in his or her official capacity;
- (4) Any DOI employee or former employee acting in his or her individual capacity when DOI or DOJ has agreed to represent that employee or pay for private representation of the employee; or

(5) The United States Government or any agency thereof, when DOJ determines that DOI is likely to be affected by the proceeding.

B. To a congressional office when requesting information on behalf of, and at the request of, the individual who is the subject of the record.

C. To the Executive Office of the President in response to an inquiry from that office made at the request of the subject of a record or a third party on that person's behalf, or for a purpose compatible with the reason for which the records are collected or maintained.

D. To any criminal, civil, or regulatory law enforcement authority (whether Federal, State, territorial, local, Tribal or foreign) when a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature, and the disclosure is compatible with the purpose for which the records were compiled.

E. To an official of another Federal agency to provide information needed in the performance of official duties related to reconciling or reconstructing data files or to enable that agency to respond to an inquiry by the individual to whom the record pertains.

F. To Federal, State, territorial, local, Tribal, or foreign agencies that have requested information relevant or necessary to the hiring, firing or retention of an employee or contractor, or the issuance of a security clearance, license, contract, grant or other benefit, when the disclosure is compatible with the purpose for which the records were compiled.

G. To representatives of the National Archives and Records Administration (NARA) to conduct records management inspections under the authority of 44 U.S.C. 2904 and 2906.

H. To State, territorial, and local governments and Tribal organizations to

provide information needed in response to court order and/or discovery purposes related to litigation, when the disclosure is compatible with the purpose for which the records were compiled.

I. To an expert, consultant, grantee, shared service provider, or contractor (including employees of the contractor) of DOI that performs services requiring access to these records on DOI's behalf to carry out the purposes of the system.

J. To appropriate agencies, entities, and persons when:

(1) DOI suspects or has confirmed that there has been a breach of the system of records;

(2) DOI has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOI (including its information systems, programs, and operations), the Federal Government, or national security; and

(3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOI's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

K. To another Federal agency or Federal entity, when DOI 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.

L. To the Office of Management and Budget (OMB) during the coordination and clearance process in connection with legislative affairs as mandated by OMB Circular A-19.

M. To the Department of the Treasury to recover debts owed to the United States.

N. To the news media and the public, with the approval of the Public Affairs Officer in consultation with counsel and the Senior Agency Official for Privacy, where there exists a legitimate public interest in the disclosure of the information, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

O. To the Internal Revenue Service for the purpose of reporting the existence of "illegal Federal irrigation subsidies" as

defined by section 90 of the Internal Revenue Code.

P. To financial institutions for the purpose of acquiring information needed by the lender to complete the certification and reporting requirements of the Reclamation Reform Act of 1982 (43 U.S.C. 390aa) for involuntarily acquired irrigable or irrigation land.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Acreage Limitation records are managed securely at Reclamation offices and the offices at water districts and contractors as required by Federal reclamation law and other regulations as stated in the Authority for Maintenance of the System section of this SORN. Paper records are contained in file folders stored in locked file cabinets at secured Reclamation facilities. Electronic records are contained in removable drives, computers, email, and electronic databases. Water districts and contractors that are required to maintain acreage limitation records abide by Reclamation requirements regarding management and storage of records.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by irrigation year; district name; landholder name; assessor parcel number; excess land sale number; acreage limitation topic to include but not limited to trusts and farm operators; operator name; employer identification number; telephone number; mailing address; or identifying property characteristics to include assessor parcel number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records in this system are currently maintained in accordance with the following Bureau of Reclamation Records Retention Schedule: 2.2.4.23 Mission—Sustainably Managed Water—Historic Water and Power Projects, Resources and Delivery PERM, which has been approved by NARA. This records schedule covers documentation including correspondence, memorandums, email, and other documentation relating to landholding limitations and determinations within Reclamation irrigation projects. The disposition for these records is permanent. Files are closed at the end of each fiscal year or when no longer needed for reference whichever is earlier. Files are transferred to NARA in Denver 25 years after closure or as volume warrants.

Certification and reporting forms (including verification forms) located in district offices are retained for 6 years, at a minimum. The most current fully

completed certification and reporting forms are maintained on file with the most current verification form, in accordance with 43 CFR 426.19(e).

Paper records are disposed of by shredding or pulping, and records contained on electronic media format are degaussed or erased in accordance with the applicable records retention schedule, NARA guidelines, and Departmental policy.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The records contained in this system are safeguarded in accordance with 43 CFR 2.226 and other applicable security rules and policies. Records are accessible only by authorized DOI employees, and other Federal government agencies and contractors who have contractual agreements with Reclamation to conduct activities related to acreage limitation. During normal hours of operation, paper records are secured in locked file cabinets under the control of authorized personnel. Computers and servers on which electronic records are stored are in secured DOI and/or contractor facilities with physical, technical, and administrative levels of security such as access codes, security codes, and security guards, to prevent unauthorized access to the DOI network and information assets. Access to DOI networks and data requires a valid username and password and is limited to DOI personnel and/or contractors who have a need to know of the information for the performance of their official duties. Access to contractor's networks and data requires restricted access limited to authorized personnel.

Computerized records systems follow the National Institute of Standards and Technology privacy and security standards as developed to comply with the Privacy Act of 1974, as amended, 5 U.S.C. 552a; Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*; Federal Information Security Modernization Act of 2014, 44 U.S.C. 3551, *et seq.*; and the Federal Information Processing Standard 199: Standards for Security Categorization of Federal Information and Information Systems. Security controls include user identification, passwords, database permissions, encryption, firewalls, audit logs, and network system security monitoring, and software controls. System administrators and authorized personnel are trained and required to follow established internal security protocols and must complete all security, privacy, and records management training and sign the DOI Rules of Behavior.

RECORD ACCESS PROCEDURES:

An individual requesting access to their records should send a written inquiry to the System Manager identified in this notice. DOI forms and instructions for submitting a Privacy Act request may be obtained from the DOI Privacy Act Requests website at <https://www.doi.gov/privacy/privacy-act-requests>. The request must include a general description of the records sought and the requester's full name, current address, and sufficient identifying information such as date of birth or other information required for verification of the requester's identity. The request must be signed and dated and be either notarized or submitted under penalty of perjury in accordance with 28 U.S.C. 1746. Requests submitted by mail must be clearly marked "PRIVACY ACT REQUEST FOR ACCESS" on both the envelope and letter. A request for access must meet the requirements of 43 CFR 2.238.

CONTESTING RECORD PROCEDURES:

An individual requesting amendment of their records should send a written request to the System Manager as identified in this notice. DOI instructions for submitting a request for amendment of records are available on the DOI Privacy Act Requests website at <https://www.doi.gov/privacy/privacy-act-requests>. The request must clearly identify the records for which amendment is being sought, the reasons for requesting the amendment, and the proposed amendment to the record. The request must include the requester's full name, current address, and sufficient identifying information such as date of birth or other information required for verification of the requester's identity. The request must be signed and dated and be either notarized or submitted under penalty of perjury in accordance with 28 U.S.C. 1746. Requests submitted by mail must be clearly marked "PRIVACY ACT REQUEST FOR AMENDMENT" on both the envelope and letter. A request for amendment must meet the requirements of 43 CFR 2.246.

NOTIFICATION PROCEDURES:

An individual requesting notification of the existence of records about them should send a written inquiry to the System Manager as identified in this notice. DOI instructions for submitting a request for notification are available on the DOI Privacy Act Requests website at <https://www.doi.gov/privacy/privacy-act-requests>. The request must include a general description of the records and the requester's full name, current address, and sufficient identifying

information such as date of birth or other information required for verification of the requester's identity. The request must be signed and dated and be either notarized or submitted under penalty of perjury in accordance with 28 U.S.C. 1746. Requests submitted by mail must be clearly marked "PRIVACY ACT INQUIRY" on both the envelope and letter. A request for notification must meet the requirements of 43 CFR 2.235.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

64 FR 13234 (March 17, 1999); modification published at 73 FR 20949 (April 17, 2008) and 86 FR 50156 (September 7, 2021).

Teri Barnett,

*Departmental Privacy Officer, U.S.
Department of the Interior.*

[FR Doc. 2024–22108 Filed 9–25–24; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–481 and 731–TA–1190 (Second Review)]

Crystalline Silicon Photovoltaic Cells and Modules From China

Determinations

On the basis of the record¹ developed in the subject five-year reviews, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that revocation of the countervailing and antidumping duty orders on crystalline silicon photovoltaic cells and modules 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 these reviews on February 1, 2024 (89 FR 6550) and determined on May 6, 2024 that it would conduct expedited reviews (89 FR 48442, June 6, 2024).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on September 20, 2024. The views of the Commission are

contained in USITC Publication 5546 (September 2024), entitled *Crystalline Silicon Photovoltaic Cells and Modules from China: Investigation Nos. 701–TA–481 and 731 TA 1190 (Second Review)*.

By order of the Commission.

Issued: September 20, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–21988 Filed 9–25–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Undersea Technology Innovation Consortium

Notice is hereby given that, on July 9, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Undersea Technology Innovation Consortium ("UTIC") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Greensea Systems, Inc., Richmond, VT; Monterey Technologies, Inc., Park City, UT; Phoenix International Holdings, Inc., Largo, MD; Enginuity Partners LLC, Middletown, RI; G Systems, Inc., Irving, TX; IDM Solutions LLC, Bristol, RI; Defense Industry Advisors LLC, St. Petersburg, FL; and Lockheed Martin Corporation, Riviera Beach, FL, have been added as parties to this venture.

Also, NKT Photonics, Inc., Boston, MA, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and UTIC intends to file additional written notifications disclosing all changes in membership.

On October 9, 2018, UTIC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 2, 2018 (83 FR 55203).

The last notification was filed with the Department on April 29, 2024. A notice was published in the **Federal**

Register pursuant to section 6(b) of the Act on June 28, 2024 (89 FR 54044).

Suzanne Morris,

*Deputy Director Civil Enforcement
Operations, Antitrust Division.*

[FR Doc. 2024–22079 Filed 9–25–24; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Resilient Infrastructure + Secure Energy Consortium

Notice is hereby given that, on July 3, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), the Resilient Infrastructure + Secure Energy Consortium ("RISE") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Wright Electric, Malta, NY; Athena Intelligence, Sacramento, CA; BCG Federal Corp., Washington, DC; Energy Storage Systems LLC, Leesburg, VA; SanPete Financial Group, Atlanta, GA; Precision Combustion, North Haven, CT; Ambri, Inc., Marlborough, MA; and ADACEN Federal LLC, Albuquerque, NM, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and RISE intends to file additional written notifications disclosing all changes in membership.

On July 2, 2021, RISE filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on August 23, 2021 (86 FR 47155).

The last notification was filed with the Department on April 1, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 28, 2024 (89 FR 54042).

Suzanne Morris,

*Deputy Director Civil Enforcement
Operations, Antitrust Division.*

[FR Doc. 2024–22070 Filed 9–25–24; 8:45 am]

BILLING CODE P

¹ The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and Production Act of 1993—Naval Surface Technology & Innovation Consortium**

Notice is hereby given that, on July 8, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Naval Surface Technology & Innovation Consortium (“NSTIC”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Accipiter Systems, Inc., Wexford, PA; AERMOR LLC, Virginia Beach, VA; CMI Defense America dba John Cockerill Defense America, Auburn Hills, MI; Enginuity Partners LLC, Middletown, RI; Exponent, Inc., Menlo Park, CA; Federal Strategies LLC, Fredericksburg, VA; Florida State University Center for Advanced Power Systems, Tallahassee, FL; G Systems, Inc., Irving, TX; Gigantor Technologies, Melbourne Beach, FL; Mantel Technologies, Inc., Fort Collins, CO; Pliant Energy Systems, Inc., Brooklyn, NY; Premier LogiTech LLC, Coppel, TX; Radio Reconnaissance Technologies, Inc., Fredericksburg, VA; Redshred LLC, Catonsville, MD; Rhea Space Activity, Inc., Washington, DC; SDA Solutions LLC, Triangle, VA; Syneren Technologies, Vienna, VA; Tapestry Solutions, San Deigo, CA; Tetrad Digital Integrity, LLC, Washington, DC; Tridentis LLC, Alexandria, VA; Wolfsped, Inc., Durham, NC; and Wright Electric, Inc., Malta, NY, have been added as parties to this venture.

Also, Advanced Hydrogen Technologies Corp., Lenoir, NC; Aquabotix Technology Corp., Jamestown, RI; HII Technical Solutions Corp., Virginia Beach, VA; Assurity Group LLC, Tampa, FL; Polaris Contract Manufacturing, Inc., Marion, MA; and GSD LLC, Williamsburg, VA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and NSTIC intends to file additional written notifications disclosing all changes in membership.

On October 8, 2019, NSTIC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 12, 2019 (84 FR 61071).

The last notification was filed with the Department on April 10, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 28, 2024 (89 FR 54045).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22074 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and Production Act of 1993—Medical CBRN Defense Consortium**

Notice is hereby given that, on July 2, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Medical CBRN Defense Consortium (“MCDC”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Alamgir Research Inc DBA ARIScience, Wayland, MA; American Additive Manufacturing LLC, Horsham, PA; Amyris Inc, Emeryville, CA; Arnasi 701 LLC, Woburn, MA; Columbus Nanoworks, Columbus, OH; Genetic Networks LLC, Miami Beach, FL; Radiation Monitoring Devices Inc, Watertown, MA; and Repurposed Therapeutics Inc, Saint Louis, MO, have been added as parties to this venture.

Also, Clarifia Inc, New York, NY; Conductive Technologies Inc, York, PA; Government Scientific Source, Reston, VA; Kleo Pharmaceuticals, New Haven, CT; Locus Biosciences, Morrisville, NC; Pertexa Healthcare Technologies, Ridgecrest, CA; SX2 Technologies LLC, Port Washington, WI; and Trauma Insight LLC dba LumaBridge LLC, San Antonio, TX, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research

project remains open, and MCDC intends to file additional written notifications disclosing all changes in membership.

On November 13, 2015, MCDC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on January 6, 2016 (81 FR 513).

The last notification was filed with the Department on April 2, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 21, 2024 (89 FR 52096).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22068 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and Production Act of 1993—Defense Electronics Consortium**

Notice is hereby given that, on July 1, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Defense Electronics Consortium (“DEC”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, BoldRF LLC, Boulder, CO; Denka America, Inc., Camden, SC; Phoenix Semiconductor Corp., Austin, TX; and Wright Electric, Malta, NY, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and DEC intends to file additional written notifications disclosing all changes in membership.

On April 12, 2023, DEC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on August 8, 2023 (88 FR 53520).

The last notification was filed with the Department on April 9, 2024. A notice was published in the **Federal**

Register pursuant to section 6(b) of the Act on June 28, 2024 (89 FR 54044).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22056 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—The Institute of Electrical and Electronics Engineers, Inc.

Notice is hereby given that, on July 1, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), The Institute of Electrical and Electronics Engineers, Inc. (“IEEE”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, 46 new standards have been initiated, and 19 existing standards are being revised. More detail regarding these changes can be found at: <https://standards.ieee.org/about/sasb/sba/20may2024/>, <https://standards.ieee.org/about/sasb/sba/06jun2024/>. The following pre-standards activities associated with IEEE Industry Connections Activities were launched or renewed: <https://standards.ieee.org/about/bog/cag/approvals/june2024/>.

On September 17, 2004, the IEEE filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 3, 2004 (69 FR 64105).

The last notification was filed with the Department on April 11, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 21, 2024 (89 FR 52090).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22058 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Senior Healthcare Innovation Consortium

Notice is hereby given that, on July 10, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Senior Healthcare Innovation Consortium (“SHIC”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Prudent Homecare, Bismarck, ND, and UnaliWear, Austin, TX, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and SHIC intends to file additional written notifications disclosing all changes in membership.

On November 02, 2022, SHIC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 23, 2022 (87 FR 71677).

The last notification was filed with the Department on April 4, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 21, 2024 (89 FR 52094).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22090 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Blockchain Security Standards Council, Inc.

Notice is hereby given that, on July 9, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Blockchain Security Standards Council, Inc. (“BSSC”) has filed written notifications

simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the identities of the parties to the venture are: Bastion Platforms, Inc., Campbell, CA; Halbourn, Inc., Miami, FL; Payward, Inc., San Francisco, CA; and Zeppelin Group Ltd., London, UNITED KINGDOM. The general area of BSSC’s planned activity is to elevate trust and confidence in blockchain systems and applications through the development and promotion of security standards and audit frameworks and to undertake such other activities as may from time to time be appropriate to further such purpose.

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22073 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—The Customer Experience Hub

Notice is hereby given that, on July 3, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), The Customer Experience Hub (“CX Hub”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Advanced Functional Fabrics of America, Inc., Cambridge, MA; Alacura Medical Transport Management, Inc., Dallas, TX; Amazon Web Services, Inc., Seattle, WA; AMPEL LLC dba AMPEL BioSolutions LLC, Charlottesville, VA; Aptima, Inc., Woburn, MA; Avsana Labs, Inc., Dallas, TX; Axiom Space, Inc., Houston, TX; Be Well Texas, San Antonio, TX; BetterAge, Sunnyside, NY; Bexar County Hospital District dba University Health System, San Antonio, TX; BioCytics, Inc., Huntersville, NC; Boyd Biomedical, Inc., Lee, MA;

Carolina BioOncology Institute PLLC, Huntersville, NC; Clinicals Global Pty Ltd., Fortitude Valley, AUSTRALIA; Cure Experience Service LLC, New York, NY; DesignPlex Biomedical LLC, Fort Worth, TX; Detroit Association of Black Organizations, Inc. (DABO), Detroit, MI; DiversiTrials, Florence, KY; Dynocardia, Inc., Cambridge, MA; Echo Investment Capital, Oklahoma City, OK; Elarex, Inc., Burlington, CANADA; Emagine Solutions Technology LLC, Tucson, AZ; Essex Management LLC, Rockville, MD; Esvyda!, Inc., Campbell, CA; Eztia Corp., Diamond Bar, CA; Focused Ultrasound Foundation, Charlottesville, VA; Galen Data, Inc., Houston, TX; GE Healthcare Technology & Innovation Center, Niskayuna, NY; Gryphon Scientific LLC, Takoma Park, MD; IA Collaborative Management Services LLC, Chicago, IL; Implementation Science Center for Cancer Control Equity (ISCCCE), Boston, MA; InnoTech Precision Medicine, Inc., Lowell, MA; Inter Astra Institute, McLean, VA; Maternal Newborn Health Innovations, PBC (MNHI), Parsippany, NJ; Maximus, Inc., McLean, VA; MediMergent LLC, Rockville, MD; Metronomic, Inc., Chantilly, VA; Mid-Atlantic Permanente Medical Group, P.C., Rockville, MD; MitoChem Therapeutics, Inc., Charleston, SC; Namida Lab, Inc., Fayetteville, AR; National Health Council, Inc., Washington, DC; NKILT Therapeutics, Inc., Springfield, NJ; Northeastern University, Boston, MA; OnKai, Inc., Boca Raton, FL; Parallax Advanced Research Corp., Beavercreek, OH; Pediatric Moonshot, Marina del Rey, CA; Proov, Erie, CO; Quorum Innovations LLC, Sarasota, FL; SANO Healthcare Consultants LLC, Ontario, CA; SEQSTER PDM, Inc., San Diego, CA; Spring Discovery, Inc., San Carlos, CA; Starling Medical, Inc., Houston, TX; SubjectWell, Inc., Austin, TX; Synthesize Consulting Group, Woodbridge, CANADA; Texas A&M University-Corpus Christi, Corpus Christi, TX; The Emmes Company LLC, Rockville, MD; The Termeer Foundation, Boston, MA; The University of Texas Health Science Center at Tyler, Tyler, TX; Touch4Life, Clarksville, MD; Triple Ring Technologies, Inc., Newark, CA; University of Connecticut Health Center, Farmington, CT; University of Illinois, Chicago, IL; University of Illinois Urbana-Champaign, Urbana, IL; University of Missouri System, Columbia, MO; University of Texas Health Science Center at Houston, Houston, TX; University of Texas Medical Branch at Galveston, Galveston,

TX; University of Texas Southwestern Medical Center, Dallas, TX; Washington Global Health Alliance, Redmond, WA; Washington University in St. Louis, St. Louis, MO; and Wiliam Marsh Rice University, Houston, TX, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CX Hub intends to file additional written notifications disclosing all changes in membership.

On January 11, 2024, CX Hub filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on April 16, 2024 (89 FR 26929).

The last notification was filed with the Department on April 17, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 21, 2024 (89 FR 52093).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22069 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Integrated Photonics Institute for Manufacturing Innovation Operating Under the Name of the American Institute for Manufacturing Integrated Photonics

Notice is hereby given that, on July 1, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), The Integrated Photonics Institute for Manufacturing Innovation, operating under the name of the American Institute for Manufacturing Integrated Photonics (“AIM Photonics”), has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Kyocera International, Inc., San Diego, CA; AdvR, Inc., Bozeman, MT; The Board of Trustees of The University of Illinois, Urbana, IL; and DeepSight Technology, Inc., Santa

Clara, CA, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and AIM Photonics intends to file additional written notifications disclosing all changes in membership.

On June 16, 2016, AIM Photonics filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on July 25, 2016 (81 FR 48450).

The last notification was filed with the Department on March 28, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 28, 2024 (89 FR 54044).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22057 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Countering Weapons of Mass Destruction

Notice is hereby given that, on July 1, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Countering Weapons of Mass Destruction (“CWMD”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, 10x National Security LLC, Leesburg, VA; BCG Federal Corp, Washington, DC; Luxfer Magtech, Inc., Cincinnati, OH; Materic LLC, Baltimore, MD; SPOC Proteomics Inc, Scottsdale, AZ; Venti LLC, New Bern, NC; and World Wide Technology LLC, St. Louis, MO, have been added as parties to this venture.

Also, Quicksilver Analytics, Inc., Hampstead, NC, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research

project remains open, and CWMD intends to file additional written notifications disclosing all changes in membership.

On January 31, 2018, CWMD filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on March 12, 2018 (83 FR 10750).

The last notification was filed with the Department on April 3, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 28, 2024 (89 FR 54043).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22059 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Maritime Sustainment and Technology Innovation Consortium

Notice is hereby given that, on July 9, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Maritime Sustainment and Technology Innovation Consortium (“MSTIC”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Specifically, Universal Solutions International, Inc., Newport News, VA; VACCO Industries, South El Monte, CA; Wolfsped, Inc., Durham, NC; Wright Electric, Inc., Malta, NY; AeroVironment, Inc., Simi Valley, CA; Agilis Measurement Systems, Inc., Palm Beach Gardens, FL; ArmorWorks Enterprises, Inc., Chandler, AZ; ASCO Power Technologies LP, Florham Park, NJ; BAE Systems Land & Armaments L.P., Minneapolis, MN; Barrow Wise Consulting LLC, Rockville, MD; C3 Technology LLC, Rochester, MN; Cigent Technology, Inc., Fort Myers, FL; CORASCloud, Inc., McLean, VA; Craiton, Inc., Vista, CA; Davidson Technologies, Inc., Huntsville, AL; ESI Acquisition Corp. DBA JA Moody, Malvern, PA; G Systems, Inc., Irving, TX; Great Plains Innovation Network,

Inc., Manhattan, KS; HumanTouch LLC, McLean, VA; Laser Welding Solutions LLC, Houston, TX; Nautical Structures Industries, Inc., Largo, FL; Penn United Technologies, Inc., Cabot, PA; Phoenix Group of Virginia, Inc., Chesapeake, VA; Reimel Machine, Inc., Willow Grove, PA; Schweitzer Engineering Laboratories, Inc., Pullman, WA; Snowbird Technologies, Inc., Jacksonville, FL; Tapestry Solutions, Inc., San Diego, CA; and Thermal and Fluids Solutions Group LLC, Fredericksburg, VA, have been added as parties to this venture.

Also, DMS South, Lancaster, TX; GSD LLC, Williamsburg, VA; and NanoVMs, Inc., San Francisco, CA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and MSTIC intends to file additional written notifications disclosing all changes in membership.

On October 21, 2020, MSTIC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 19, 2020 (85 FR 73750).

The last notification was filed with the Department on April 15, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 28, 2024 (89 FR 54041).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22075 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Decentralized Storage Alliance Association

Notice is hereby given that, on July 1, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Decentralized Storage Alliance Association (“DSAA”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages

under specified circumstances. Specifically, FilStor, Inc., Cranford, NJ, and Titan Foundation, Grand Cayman, CAYMAN ISLANDS, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and DSAA intends to file additional written notifications disclosing all changes in membership.

On August 1, 2023, DSAA filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on October 6, 2023 (88 FR 69670).

The last notification was filed with the Department on October 17, 2023. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on December 15, 2023 (88 FR 86931).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024–22055 Filed 9–25–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—UHD Alliance

Notice is hereby given that, on July 8, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), UHD Alliance, Inc. (“UHD Alliance”) filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Disney Streaming Services LLC, Burbank, CA, has been added as a party to this venture.

Also, Portrait Displays, Inc., Pleasanton, CA, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and UHD Alliance intends to file additional written notifications disclosing all changes in membership.

On June 17, 2015, UHD Alliance filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on July 17, 2015 (80 FR 42537).

The last notification was filed with the Department on May 6, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 21, 2024 (89 FR 52094).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2024-22077 Filed 9-25-24; 8:45 am]

BILLING CODE 4410-11-P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Information Advisory Council

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of a virtual WIAC meeting November 6, 2024.

SUMMARY: Notice is hereby given that the Workforce Information Advisory Council (WIAC or Advisory Council) will meet virtually November 6, 2024. Information for public attendance will be posted at www.dol.gov/agencies/eta/wioa/wiac/meetings several days prior to the meeting date. The meeting will be open to the public.

DATES: The meeting will take place November 6, 2024. The meeting will begin at 3 p.m. EST and conclude at approximately 5 p.m. EST. Public statements and requests for special accommodations or to address the Advisory Council must be received by 5 p.m. EST Monday, November 4, 2024.

ADDRESSES: The meeting will be held virtually. Registration and information for the public to attend this virtual meeting will be posted on the WIAC website, www.dol.gov/agencies/eta/wioa/wiac/meetings. If problems arise accessing the meeting, please contact Donald Haughton, Unit Chief in the Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, at 202-203-9209.

FOR FURTHER INFORMATION CONTACT: Steven Rietzke, Chief, Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, Room C-4510, 200 Constitution Ave. NW, Washington, DC

20210; Telephone: 202-693-3912; Email: WIAC@dol.gov. Mr. Rietzke is the WIAC Designated Federal Officer.

SUPPLEMENTARY INFORMATION:

Background: This meeting is being held pursuant to section 308 of the Workforce Innovation and Opportunity Act of 2014 (WIOA) (Pub. L. 113-128), which amends section 15 of the Wagner-Peyser Act of 1933 (29 U.S.C. 491-2). The WIAC is an important component of WIOA. The WIAC is a Federal advisory committee of workforce and labor market information experts representing a broad range of national, state, and local data and information users and producers. The WIAC was established in accordance with provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. app.) and will act in accordance with the applicable provisions of FACA and its implementing regulation at 41 CFR 102-3. The purpose of the WIAC is to provide recommendations to the Secretary of Labor (Secretary), working jointly through the Assistant Secretary for Employment and Training and the Commissioner of Labor Statistics, to address: (1) the evaluation and improvement of the nationwide workforce and labor market information (WLMI) system and statewide systems that comprise the nationwide system; and (2) how the Department of Labor (Department) and the states will cooperate in the management of those systems. These systems include programs to produce employment-related statistics and state and local WLMI.

The Department anticipates the WIAC will accomplish its objectives by: (1) studying WLMI issues; (2) seeking and sharing information on innovative approaches, new technologies, and data to inform employment, skills training, and workforce and economic development decision making and policy; and (3) advising the Secretary on how the WLMI system can best support workforce development, planning, and program development. Additional information is available at www.dol.gov/agencies/eta/wioa/wiac/meetings.

Purpose: The WIAC is continually identifying and reviewing issues and aspects of the WLMI system and statewide systems that comprise the nationwide system and how the Department and the states will cooperate in the management of those systems. As part of this process, the Advisory Council meets to gather information and to engage in deliberative and planning activities to facilitate the development and provision

of its recommendations to the Secretary in a timely manner.

Agenda: There are three agenda topics for this meeting. One, review and approve recommendations the WIAC members discussed at the previous meeting held September 9 and 10, 2024. Two, discuss topics for future consideration of the WIAC. Third, determine a workplan for developing the next set of WIAC recommendations. A detailed agenda will be available at www.dol.gov/agencies/eta/wioa/wiac/meetings shortly before the November 6, 2024, meeting commences.

The Advisory Council will open the floor for public comment at approximately 4 p.m. EST for approximately 10 minutes. However, that time may change at the WIAC chair's discretion.

Attending the Meetings: Members of the public who require reasonable accommodations to attend the virtual meeting may submit requests for accommodations via email to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line "November 2024 WIAC Meeting Accommodations" by the date indicated in the **DATES** section. Please include a specific description of the accommodations requested and phone number or email address where you may be contacted if additional information is needed to meet your request.

Public Statements: Organizations or members of the public wishing to submit written statements may do so by transmitting them as email attachments in PDF format to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line "November 2024 WIAC Meeting Public Statements" by the date indicated in the **DATES** section. Submitters may include their name and contact information in the body of the email for statements transmitted electronically. Relevant statements received before the date indicated in the **DATES** section will be included in the record of each meeting. No deletions, modifications, or redactions will be made to statements received, as they are public records. Please do not include personally identifiable information in your public statement.

Requests to Address the Advisory Council: Members of the public or representatives of organizations wishing to address the Advisory Council should forward their requests to the contact indicated in the **FOR FURTHER INFORMATION CONTACT** section, or contact the same by phone, by the date indicated in the **DATES** section. Oral presentations will be limited to 10

minutes, time permitting, and shall proceed at the discretion of the Advisory Council chair. Individuals with disabilities, or others who need special accommodations, should indicate their needs along with their request.

José Javier Rodríguez,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2024–22101 Filed 9–25–24; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2024–0003]

Ballard Marine Construction Lower Olentangy Tunnel Project; Grant of Permanent Variance

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA grants a permanent variance to Ballard Marine Construction (Ballard) related to work in compressed air environments.

DATES: The permanent variance specified by this notice becomes effective on September 26, 2024 and shall remain in effect until the completion of the Lower Olentangy Tunnel Project or until modified or revoked by OSHA.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: meilinger.frank@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor; telephone: (202) 693–1911; email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

Copies of this Federal Register notice. Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's web page at <http://www.osha.gov>.

I. Overview

On April 11, 2023, Ballard Marine Construction (Ballard or the applicant), submitted under section 6(d) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655, and 29 CFR 1905.11 (Variances and other relief under Section 6(d)) an application for a permanent variance from several provisions of the OSHA standard that regulates work in compressed air, 1926.803 of 1926 subpart S—Underground Construction, Caissons, Cofferdams, and Compressed Air, and an interim order allowing it to proceed while OSHA considers the request for a permanent variance (OSHA–2024–0003–0002). This notice addresses Ballard's application for a permanent variance and interim order for construction of the Lower Olentangy Tunnel Project in Columbus, Ohio only and is not applicable to future Ballard tunneling projects.

This notice addresses Ballard's application for a permanent variance and interim order from the provisions of the standard that: (1) require the use of the decompression values specified in decompression tables in appendix A of subpart S (29 CFR 1926.803(f)(1)); and (2) require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and (xvii), respectively).

OSHA reviewed Ballard's application for the variance and interim order and determined that they were appropriately submitted in compliance with the applicable variance procedures in Section 6(d) of the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 655) and OSHA's regulations at 29 CFR 1905.11 (Variances and other relief under section 6(d)), including the requirement that the applicant inform workers and their representatives of their rights to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

OSHA reviewed the alternative procedures in Ballard's application and preliminarily determined that the applicant's proposed alternatives, on the whole, subject to the conditions in the request and imposed by the interim order, provide measures that are as safe and healthful as those required by the cited OSHA standards. On March 27, 2024, OSHA published a **Federal Register** notice announcing Ballard's application for permanent variance, stating the preliminary determination along with the basis of that determination, and granting the interim

order (89 FR 21274). OSHA requested comments on each.

OSHA did not receive any comments or other information disputing the preliminary determination that the alternatives were at least as safe as OSHA's standard, nor any objections to OSHA granting a permanent variance. Accordingly, through this notice OSHA grants a permanent variance, subject to the conditions set out in this document.

A. Background

The information that follows about Ballard, its methods, and the Lower Olentangy Tunnel Project comes from the Ballard variance application.

Ballard is a contractor for the Lower Olentangy Tunnel Project (the project), that works on complex tunnel projects using innovations in tunnel-excavation methods. The applicant's workers engage in the construction of tunnels using advanced shielded mechanical excavation techniques in conjunction with an earth pressure balanced micro-tunnel boring machine (TBM). Using shielded mechanical excavation techniques, in conjunction with precast concrete tunnel liners and backfill grout, TBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face through various geologies and isolate that pressure to the forward section (the working chamber) of the TBM.

Ballard asserts that it bores tunnels using a TBM at levels below the water table through soft soils consisting of clay, silt, and sand. TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. The forward-most portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the TBM. Within the shield, the working chamber consists of two sections: the forward working chamber and the staging chamber. The forward working chamber is immediately behind the cutter head and tunnel face. The staging chamber is behind the forward working chamber and between the man-lock door and the entry door to the forward working chamber.

The TBM has twin man-locks located between the pressurized working chamber and the non-pressurized portion of the machine. Each man-lock has two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel

to access the man-locks if required in an emergency.

Ballard's Hyperbaric Operations Manual (HOM) for the Lower Olentangy Tunnel Project indicates that the maximum pressure to which it is likely to expose workers during project interventions for the three tunnel drives is 27 pounds per square inch gauge (p.s.i.g.). The applicant will pressurize the working chamber to the level required to maintain a stable tunnel face, which for this project Ballard estimates will be up to a pressure not exceeding 27 p.s.i.g., which does not exceed the maximum pressure specified by the OSHA standard at 29 CFR 1926.803(e)(5).¹ Ballard is not seeking a variance from this provision of the compressed-air standard.

Ballard employs specially trained personnel for the construction of the tunnel. To keep the machinery working effectively, Ballard asserts that these workers must periodically enter the excavation working chamber of the TBM to perform hyperbaric interventions during which workers would be exposed to air pressures up to 27 p.s.i.g., which does not exceed the maximum pressure specified by the existing OSHA standard at 29 CFR 1926.803(e)(5). These interventions consist of conducting inspections or maintenance work on the cutter-head structure and cutting tools of the TBM, such as changing replaceable cutting tools and disposable wear bars, and, in rare cases, repairing structural damage to the cutter head. These interventions are the only time that workers are exposed to compressed air. Interventions in the excavation working chamber (the pressurized portion of the TBM) take place only after halting tunnel excavation and preparing the machine and crew for an intervention.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The man-locks and the working chamber are designed to accommodate three people, which is the maximum crew size allowed under the permanent variance. When the required decompression times are greater than work times, the twin man-locks allow for crew rotation.

During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

Ballard asserts that these innovations in tunnel excavation have greatly reduced worker exposure to hazards of pressurized air work because they have eliminated the need to pressurize the entire tunnel for the project and thereby reduce the number of workers exposed, as well as the total duration of exposure, to hyperbaric pressure during tunnel construction. These advances in technology have substantially modified the methods used by the construction industry to excavate subaqueous tunnels compared to the caisson work regulated by the current OSHA compressed-air standard for construction at 29 CFR 1926.803.

In addition to the reduced exposures resulting from the innovations in tunnel-excavation methods, Ballard asserts that innovations in hyperbaric medicine and technology improve the safety of decompression from hyperbaric exposures. These procedures, however, deviate from the decompression process that OSHA requires for construction in 29 CFR 1926.803(f)(1) and the decompression tables in appendix A of 29 CFR 1926, subpart S. Nevertheless, according to Ballard, their use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the decompression tables specified by the existing OSHA standard.

Ballard contends that the alternative safety measures included in the application provide Ballard's workers with a place of employment that is at least as safe as they would be under OSHA's compressed-air standard for construction. Ballard also provided OSHA a project-specific HOM (OSHA–2024–0003–0003) for the Lower Olentangy Tunnel Project that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained man-lock attendants and hyperbaric or compressed-air workers to support their assertions of equivalency in worker protection.

OSHA included all of the above information in the **Federal Register** notice announcing Ballard's variance application and did not receive any comments disputing any of that information, including the safety assertions made by Ballard in the variance application.

II. The Variance Application

Pursuant to the requirements of OSHA's variance regulations (29 CFR 1905.11), the applicant has certified that it notified its affected workers² of the variance application and request for interim order by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application. In addition, the applicant has certified that it informed its workers of their right to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

III. OSHA History of Approval of Nearly Identical Variance Requests

OSHA has previously approved several nearly identical variances involving the same types of tunneling equipment used for similar projects (tunnel construction variances). OSHA notes that it granted several subaqueous tunnel construction permanent variances from the same provisions of OSHA's compressed-air standard (29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii)) that are the subject of the present application: (1) Traylor JV for the completion of the Blue Plains Tunnel in Washington, DC (80 FR 16440 (March 27, 2015)); (2) Impregilo, Healy, Parsons, Joint Venture (IHP JV) for the completion of the Anacostia River Tunnel in Washington, DC (80 FR 50652 (August 20, 2015)); (3) Tully/OHL USA Joint Venture for the completion of the New York Economic Development Corporation's New York Siphon Tunnel project (79 FR 29809 (May 23, 2014)); (4) Salini-Impregilo/Healy Joint Venture for the completion of the Northeast Boundary Tunnel in Washington, DC (85 FR 27767, (May 11, 2020)); (5) McNally/Kiewit SST Joint Venture for the completion of the Shoreline Storage Tunnel Project in Cleveland, Ohio (88 FR 15080, March 10, 2023); (6) Traylor-Shea Joint Venture for the completion of the Alexandria River Renew Tunnel Project in Alexandria Virginia and Washington DC (88 FR 15080, March 10, 2023); and (7) Ballard Marine Construction for the completion of the Bay Park Tunnel Project (89 FR 8442, February 7, 2024). The proposed alternate conditions in this notice are nearly identical to the alternate conditions of the previous permanent variances.³ OSHA is not aware of any

¹ The decompression tables in Appendix A of subpart S express the working pressures as pounds per square inch gauge (p.s.i.g.). Therefore, throughout this notice, OSHA expresses the p.s.i. value specified by 29 CFR 1926.803(e)(5) as p.s.i.g., consistent with the terminology in appendix A, table 1 of subpart S.

² See the definition of "Affected employee or worker" in section VII.C of this Notice.

³ The previous tunnel construction variances allowed further deviation from OSHA standards by

injuries or other safety issues that arose from work performed under these conditions in accordance with the previous variances.

IV. Applicable OSHA Standard and the Relevant Variance

A. Variance From Paragraph (f)(1) of 29 CFR 1926.803, Requirement To Use OSHA Decompression Tables

OSHA's compressed-air standard for construction requires decompression in accordance with the decompression tables in Appendix A of 29 CFR 1926, subpart S (see 29 CFR 1926.803(f)(1)). As an alternative to the OSHA decompression tables, the applicant proposes to use newer decompression schedules (the 1992 French Decompression Tables) that rely on staged decompression and supplement breathing air used during decompression with air or oxygen (as appropriate).⁴ The applicant asserts decompression protocols using the 1992 French Decompression Tables for air or oxygen as specified by the Integrated Pipeline Tunnel Project-specific HOM are safer for tunnel workers than the decompression protocols specified in appendix A of 29 CFR 1926 subpart S. Accordingly, the applicant commits to following the decompression procedures described in that HOM, which requires Ballard to follow the 1992 French Decompression Tables to decompress compressed air workers (CAWs) after they exit the hyperbaric conditions in the working chamber.

Depending on the maximum working pressure and exposure times, the 1992 French Decompression Tables provide for air decompression with or without oxygen. Ballard asserts that oxygen decompression has many benefits, including (1) keeping the partial pressure of nitrogen in the lungs as low as possible; (2) keeping external pressure as low as possible to reduce the formation of gas bubbles in the blood; (3) removing nitrogen from the lungs and arterial blood and increasing the rate of nitrogen elimination; (4)

improving the quality of breathing during decompression stops so that workers are less tired and to prevent bone necrosis; (5) reducing decompression time by approximately 33 percent as compared to air decompression; and (6) reducing inflammation.

In addition, the project-specific HOM requires a physician, certified in hyperbaric medicine, to manage the medical condition of CAWs during hyperbaric exposures and decompression. A trained and experienced man-lock attendant is also required to be present during hyperbaric exposures and decompression. This man-lock attendant is to operate the hyperbaric system to ensure compliance with the specified decompression table. A hyperbaric supervisor, who is trained in hyperbaric operations, procedures, and safety, directly oversees all hyperbaric interventions, and ensures that staff follow the procedures delineated in the HOM or by the attending physician.

B. Variance From Paragraph (g)(1)(iii) of 29 CFR 1926.803, Automatically Regulated Continuous Decompression

Ballard seeks a permanent variance from the OSHA standard at 29 CFR 1926.803(g)(1)(iii), which requires automatic controls to regulate decompression. As noted above, the applicant is conducting the staged decompression according to the 1992 French Decompression Tables under the direct control of the trained man-lock attendant and under the oversight of the hyperbaric supervisor.

Breathing air under hyperbaric conditions increases the amount of nitrogen gas dissolved in a CAW's tissues. The greater the hyperbaric pressure under these conditions and the more time spent under the increased pressure, the greater the amount of nitrogen gas is dissolved in the tissues. When the pressure decreases during decompression, tissues release the dissolved nitrogen gas into the blood system, which then carries the nitrogen gas to the lungs for elimination through exhalation. Releasing hyperbaric pressure too rapidly during decompression can increase the size of the bubbles formed by nitrogen gas in the blood system, resulting in decompression illness (DCI), commonly referred to as "the bends." This description of the etiology of DCI is consistent with current scientific theory and research on the issue.

The 1992 French Decompression Tables, proposed for use by the applicant, provide for stops during worker decompression (*i.e.*, staged

decompression) to control the release of nitrogen gas from tissues into the blood system. Studies show that staged decompression, in combination with other features of the 1992 French Decompression Tables such as the use of oxygen, result in a lower incidence of DCI than the use of automatically regulated continuous decompression.⁵ In addition, the applicant asserts that staged decompression administered in accordance with its HOM is at least as effective as an automatic controller in regulating the decompression process because the HOM requires a hyperbaric supervisor who directly supervises all hyperbaric interventions and ensures that the man-lock attendant, who is a competent person in the manual control of hyperbaric systems, follows the schedule specified in the decompression tables, including stops.

C. Variance From Paragraph (g)(1)(xvii) of 29 CFR 1926.803, Requirement of Special Decompression Chamber

The OSHA compressed-air standard for construction requires employers to use a special decompression chamber of sufficient size to accommodate all CAWs being decompressed at the end of the shift when total decompression time exceeds 75 minutes (see 29 CFR 1926.803(g)(1)(xvii)). Use of the special decompression chamber enables CAWs to move about and flex their joints to prevent neuromuscular problems during decompression.

Space limitations in the TBM do not allow for the installation and use of an additional special decompression lock or chamber. The applicant proposes that

⁵ See, *e.g.*, Dr. Eric Kindwall, EP (1997), Compressed air tunneling and caisson work decompression procedures: development, problems, and solutions. *Undersea and Hyperbaric Medicine*, 24(4), pp. 337–345. This article reported 60 treated cases of DCI among 4,168 exposures between 19 and 31 p.s.i.g. over a 51-week contract period, for a DCI incidence of 1.44% for the decompression tables specified by the OSHA standard. Dr. Kindwall notes that the use of automatically regulated continuous decompression in the Washington State safety standards for compressed-air work (from which OSHA derived its decompression tables) was at the insistence of contractors and the union, and against the advice of the expert who calculated the decompression table and recommended using staged decompression. Dr. Kindwall then states, "Continuous decompression is inefficient and wasteful. For example, if the last stage from 4 p.s.i.g. . . . to the surface took 1h, at least half the time is spent at pressures less than 2 p.s.i.g. . . ., which provides less and less meaningful bubble suppression" In addition, Dr. Kindwall addresses the continuous-decompression protocol in the OSHA compressed-air standard for construction, noting that "[a]side from the tables for saturation diving to deep depths, no other widely used or officially approved diving decompression tables use straight line, continuous decompressions at varying rates. Stage decompression is usually the rule, since it is simpler to control."

permitting employee exposures above 50 p.s.i.g., based on the composition of the soil and the amount of water that will be above the tunnel for various sections of this project. The current permanent variance includes substantively the same safeguards as the variances that OSHA granted previously even though employees will not be exposed to pressures higher than 27 p.s.i.g.

⁴ In 1992, the French Ministry of Labour replaced the 1974 French Decompression Tables with the 1992 French Decompression Tables, which differ from OSHA's decompression tables in appendix A by using: (1) staged decompression as opposed to continuous (linear) decompression; (2) decompression tables based on air or both air and pure oxygen; and (3) emergency tables when unexpected exposure times occur (up to 30 minutes above the maximum allowed working time).

it be permitted to rely on the man-locks and staging chamber in lieu of adding a separate, special decompression chamber. Because only a few workers out of the entire crew are exposed to hyperbaric pressure, the man-locks (which, as noted earlier, connect directly to the working chamber) and the staging chamber are of sufficient size to accommodate all of the exposed workers during decompression. The applicant uses the existing man-locks, each of which adequately accommodates a three-member crew for this purpose when decompression lasts up to 75 minutes. When decompression exceeds 75 minutes, crews can open the door connecting the two compartments in each man-lock (during decompression stops) or exit the man-lock and move into the staging chamber where additional space is available. The applicant asserts that this alternative arrangement is as effective as a special decompression chamber in that it has sufficient space for all the CAWs at the end of a shift and enables the CAWs to move about and flex their joints to prevent neuromuscular problems.

V. Decision

After reviewing the proposed alternatives, OSHA has determined that the applicant's proposed alternatives, on the whole, subject to the conditions in the request and imposed by this permanent variance, provide measures that are as safe and healthful as those required by the cited OSHA standards addressed in section IV of this notice.

In addition, OSHA has determined that each of the following alternatives are at least as effective as the specified OSHA requirements:

A. 29 CFR 1926.803(f)(1)

The applicant has proposed to implement equally effective alternative measures to the requirement in 29 CFR 1926.803(f)(1) for compliance with OSHA's decompression tables. The HOM specifies the procedures and personnel qualifications for performing work safely during the compression and decompression phases of interventions. The HOM also specifies the decompression tables the applicant proposes to use (the 1992 French Decompression Tables). Depending on the maximum working pressure and exposure times during the interventions, the tables provide for decompression using air, pure oxygen, or a combination of air and oxygen. The decompression tables also include delays or stops for various time intervals at different pressure levels during the transition to atmospheric pressure (*i.e.*, staged decompression). In all cases, a

physician certified in hyperbaric medicine will manage the medical condition of CAWs during decompression. In addition, a trained and experienced man-lock attendant, experienced in recognizing decompression sickness or illnesses and injuries, will be present. Of key importance, a hyperbaric supervisor, trained in hyperbaric operations, procedures, and safety, will directly supervise all hyperbaric operations to ensure compliance with the procedures delineated in the project-specific HOM or by the attending physician.

Prior to granting the seven previous permanent variances to Traylor JV, IHP JV, Tully/OHL JV, Salini-Impregilo/Healy JV, McNally/Kiewit SST JV, Traylor Shea JV, and Ballard Marine Bay Park Tunnel New York, OSHA conducted a review of the scientific literature and concluded that the alternative decompression method (*i.e.*, the 1992 French Decompression Tables) Ballard proposed would be at least as safe as the decompression tables specified by OSHA when applied by trained medical personnel under the conditions imposed by the permanent variance.

Some of the literature indicates that the alternative decompression method may be safer, concluding that decompression performed in accordance with these tables resulted in a lower occurrence of DCI than decompression conducted in accordance with the decompression tables specified by the standard. For example, H.L. Anderson studied the occurrence of DCI at maximum hyperbaric pressures ranging from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark (1992–1996).⁶ This project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Anderson observed 6 DCI cases out of 7,220 decompression events and reported that switching to the 1992 French Decompression tables reduced the DCI incidence to 0.08% compared to a previous incidence rate of 0.14%. The DCI incidence in the study by H.L. Anderson is substantially less than the DCI incidence reported for the decompression tables specified in appendix A.

OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were

⁶ Anderson HL (2002). Decompression sickness during construction of the Great Belt tunnel, Denmark. *Undersea and Hyperbaric Medicine*, 29(3), pp. 172–188.

higher than the DCI incidence reported for the OSHA decompression tables.⁷

OSHA's experience with the previous seven variances, which all incorporated nearly identical decompression plans and did not result in safety issues, also provides evidence that the alternative procedure as a whole is at least as effective for this type of tunneling project as compliance with OSHA's decompression tables. The experience of State Plans⁸ that granted variances (Nevada, Oregon and Washington)⁹ for hyperbaric exposures occurring during similar subaqueous tunnel-construction work provide additional evidence of the effectiveness of this alternative procedure.

B. 29 CFR 1926.803(g)(1)(iii)

The applicant developed, and proposed to implement, an equally effective alternative to 29 CFR 1926.803(g)(1)(iii), which requires the use of automatic controllers that continuously decrease pressure to achieve decompression in accordance with the tables specified by the standard. The applicant's alternative includes using the 1992 French Decompression Tables for guiding staged decompression to achieve lower occurrences of DCI, using a trained and competent attendant for implementing appropriate hyperbaric entry and exit procedures, and providing a competent hyperbaric supervisor and attending physician certified in hyperbaric medicine to oversee all hyperbaric operations.

In reaching this conclusion, OSHA again notes the experience of previous nearly identical tunneling variances, the experiences of States with OSHA-approved State Plans, and a review of the literature and other information noted earlier.

⁷ Le Péchon JC, Barre P, Baud JP, Ollivier F (September 1996). Compressed air work—French Tables 1992—operational results. *JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS*, pp. 1–5 (see Ex. OSHA–2012–0036–0005).

⁸ Section 18 of the OSH Act, Congress expressly provides that States and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to States and territories which have developed and are operating their own job safety and health programs as “States with OSHA-approved State Plans.” Their programs must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards (29 U.S.C. 667).

⁹ These State variances are available in the docket for the 2015 Traylor JV variance: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0005 (Oregon), and OSHA–2012–0035–0004 (Washington).

C. 29 CFR 1926.803(g)(1)(xvii)

The applicant developed, and proposed to implement, an effective alternative to the use of the special decompression chamber required by 29 CFR 1926.803(g)(1)(xvii). The TBM's man-lock and working chamber appear to satisfy all of the conditions of the special decompression chamber, including that they provide sufficient space for the maximum crew of three CAWs to stand up and move around, and safely accommodate decompression times up to 360 minutes. Therefore, again noting OSHA's previous experience with nearly identical variances including the same alternative, OSHA preliminarily determined that the TBM's man-lock and working chamber function as effectively as the special decompression chamber required by the standard.

Based on a review of available evidence, the experience of State Plans that granted variances (Nevada, Oregon, and Washington)¹⁰ for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, and the information provided in the applicant's variance application, OSHA is granting the permanent variance.

Pursuant to Section 6(d) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(d)), and based on the record discussed above, the agency finds that when Ballard complies with the conditions of the following order, the working conditions of the workers are at least as safe and healthful as if it complied with the working conditions specified by paragraphs (f)(1), (g)(1)(iii), and (g)(1)(xvii) of 29 CFR 1926.803. Therefore, Ballard must: (1) comply with the conditions listed below under "Conditions Specified for the Permanent Variance" for the period between the date of this notice and completion of the Lower Olentangy Tunnel Project; (2) comply fully with all other applicable provisions of 29 CFR part 1926; and (3) provide a copy of this **Federal Register** notice to all employees affected by the conditions, including the affected employees of other employers, using the same means it used to inform these employees of the application for a permanent variance. Additionally, this order will remain in effect until one of the following conditions occurs: (1) completion of the Lower Olentangy Tunnel Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

VI. Description of the Specified Conditions for the Permanent Variance

The conditions for the variance are set out in the Order at the end of this document. This section provides additional detail regarding the conditions in the Order.

Condition A: Scope

The scope of the permanent variance limits coverage to the work situations specified. Clearly defining the scope of the permanent variance provides Ballard, Ballard's employees, potential future applicants, other stakeholders, the public, and OSHA with necessary information regarding the work situations in which the permanent variance applies. To the extent that Ballard exceeds the defined scope of this variance, it will be required to comply with OSHA's standards. This permanent variance applies only to the applicant, Ballard, and only to the remainder of construction work on the Lower Olentangy Tunnel Project.

Condition B: List of Abbreviations

Condition B defines abbreviations used in the permanent variance. OSHA believes that defining these abbreviations serves to clarify and standardize their usage, thereby enhancing the applicant's and its employees' understanding of the conditions specified by the permanent variance.

Condition C: Definitions

The condition defines a series of terms, mostly technical terms, used in the permanent variance to standardize and clarify their meaning. OSHA believes that defining these terms serves to enhance the applicant's and its employees' understanding of the conditions specified by the permanent variance.

Condition D: Safety and Health Practices

This condition requires the applicant to develop and submit to OSHA an HOM specific to the Lower Olentangy Tunnel Project at least six months before using the TBM for tunneling operations. The applicant must also submit, at least six months before using the TBM, proof that the TBM's hyperbaric chambers have been designed, fabricated, inspected, tested, marked, and stamped in accordance with the requirements of ASME PVHO-1.2019 (or the most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*). These requirements ensure that the applicant develops hyperbaric safety and health procedures suitable for the project.

The submission of the HOM enables OSHA to determine whether the safety and health instructions and measures it specifies are appropriate to the field conditions of the tunnel (including expected geological conditions), conform to the conditions of the variance, and adequately protect the safety and health of the CAWs. It also facilitates OSHA's ability to ensure that the applicant is complying with these instructions and measures. The requirement for proof of compliance with ASME PVHO-1.2019 is intended to ensure that the equipment is structurally sound and capable of performing to protect the safety of the employees exposed to hyperbaric pressure. The applicant has submitted the HOM and proof of compliance with ASME PVHO-1.2019.

Additionally, the condition includes a series of related hazard prevention and control requirements and methods (e.g., decompression tables, job hazard analyses (JHA), operations and inspections checklists, incident investigation, and recording and notification to OSHA of recordable hyperbaric injuries and illnesses) designed to ensure the continued effective functioning of the hyperbaric equipment and operating system.

Condition E: Communication

This condition requires the applicant to develop and implement an effective system of information sharing and communication. Effective information sharing and communication are intended to ensure that affected workers receive updated information regarding any safety-related hazards and incidents, and corrective actions taken, prior to the start of each shift. The condition also requires the applicant to ensure that reliable means of emergency communications are available and maintained for affected workers and support personnel during hyperbaric operations. Availability of such reliable means of communications enables affected workers and support personnel to respond quickly and effectively to hazardous conditions or emergencies that may develop during TBM operations.

Condition F: Worker Qualification and Training

This condition requires the applicant to develop and implement an effective qualification and training program for affected workers. The condition specifies the factors that an affected worker must know to perform safely during hyperbaric operations, including how to enter, work in, and exit from hyperbaric conditions under both

¹⁰ These state variances are available in the docket: Exs. OSHA-2012-0035-0006 (Nevada), OSHA-2012-0035-0007 (Oregon), and OSHA-2012-0035-0008 (Washington).

normal and emergency conditions. Having well-trained and qualified workers performing hyperbaric intervention work is intended to ensure that they recognize, and respond appropriately to, hyperbaric safety and health hazards. These qualification and training requirements enable affected workers to cope effectively with emergencies, as well as the discomfort and physiological effects of hyperbaric exposure, thereby preventing worker injury, illness, and fatalities.

Paragraph (2)(e) of this condition requires the applicant to provide affected workers with information they can use to contact the appropriate healthcare professionals if the workers believe they are developing hyperbaric-related health effects. This requirement provides for early intervention and treatment of DCI and other health effects resulting from hyperbaric exposure, thereby reducing the potential severity of these effects.

Condition G: Inspections, Tests, and Accident Prevention

Condition G requires the applicant to develop, implement, and operate a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems, and associated work areas. This condition helps to ensure the safe operation and physical integrity of the equipment and work areas necessary to conduct hyperbaric operations. The condition also enhances worker safety by reducing the risk of hyperbaric-related emergencies.

Paragraph (3) of this condition requires the applicant to document tests, inspections, corrective actions, and repairs involving the TBM, and maintain these documents at the jobsite for the duration of the job. This requirement provides the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects in hyperbaric equipment and systems were appropriate, prior to returning them to service.

Condition H: Compression and Decompression

This condition requires the applicant to consult with the designated medical advisor regarding special compression or decompression procedures appropriate for any unacclimated CAW and then implement the procedures recommended by the medical advisor. This proposed provision ensures that the applicant consults with the medical advisor, and involves the medical

advisor in the evaluation, development, and implementation of compression or decompression protocols appropriate for any CAW requiring acclimation to the hyperbaric conditions encountered during TBM operations. Accordingly, CAWs requiring acclimation have an opportunity to acclimate prior to exposure to these hyperbaric conditions. OSHA believes this condition will prevent or reduce adverse reactions among CAWs to the effects of compression or decompression associated with the intervention work they perform in the TBM.

Condition I: Recordkeeping

Under OSHA's recordkeeping requirements in 29 CFR part 1904 regarding Recording and Reporting Occupational Injuries and Illnesses, the employer must maintain a record of any recordable injury, illness, or fatality (as defined by 29 CFR part 1904) resulting from exposure of an employee to hyperbaric conditions, or any other work condition, by completing the OSHA Form 301 Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses. The applicant did not seek a variance from this standard and therefore Ballard must comply fully with those requirements.

Examples of important information to include on the OSHA Form 301 Injury and Illness Incident Report (along with the corresponding questions on the form) are:

Q14

- the task performed;
- the composition of the gas mixture (e.g., air or oxygen);
- an estimate of the CAW's workload;
- the maximum working pressure;
- temperature in the work and decompression environments;
- unusual occurrences, if any, during the task or decompression

Q15

- time of symptom onset;
- duration between decompression and onset of symptoms

Q16

- type and duration of symptoms;
- a medical summary of the illness or injury

Q17

- duration of the hyperbaric intervention;
- possible contributing factors;
- the number of prior interventions completed by the injured or ill CAW;

and the pressure to which the CAW was exposed during those interventions.¹¹

Condition J below adds additional reporting responsibilities, beyond those already required by the OSHA standard. The applicant is required to maintain records of specific factors associated with each hyperbaric intervention. The information gathered and recorded under Condition J, in concert with the information provided under Condition I (using OSHA Form 301 Injury and Illness Incident Report to investigate and record hyperbaric recordable injuries as defined by 29 CFR 1904.4, 1904.7, and 1904.8 -.12), enables the applicant and OSHA to assess the effectiveness of the permanent variance in preventing DCI and other hyperbaric-related effects.

Condition J: Notifications

Under the notifications condition, the applicant is required, within specified periods of time, to notify OSHA of: (1) any recordable injury, illness, in-patient hospitalization, amputation, loss of an eye, or fatality that occurs as a result of hyperbaric exposures during TBM operations; and in-patient hospitalization, amputation, loss of an eye or fatality that occurs during other operations must also be reported pursuant to 29 CFR 1910.39(a); (2) provide OSHA a copy of the hyperbaric exposures incident investigation report (using OSHA Form 301 Injury and Illness Incident Report) of these events within 24 hours of the incident; (3) include on OSHA Form 301 Injury and Illness Incident Report information on the hyperbaric conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented; (4) provide the certification that affected workers were informed of the incident and the results of the incident investigation; (5) notify OSHA's Office of Technical Programs and Coordination Activities (OTPCA) and the OSHA Area Office in Columbus, Ohio within 15 working days should the applicant need to revise the HOM to accommodate changes in its compressed-air operations that affect Ballard's ability to comply with the conditions of the permanent variance; and (6) provide OTPCA and the OSHA Area Office in Columbus, Ohio, at the end of the project, with a report evaluating the effectiveness of the decompression tables.

¹¹ See 29 CFR 1904 Recording and Reporting Occupational Injuries and Illnesses (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631); recordkeeping forms and instructions <https://www.osha.gov/recordkeeping/forms>.

It should be noted that the requirement for completing and submitting the hyperbaric exposure-related (recordable) incident investigation report (OSHA 301 Injury and Illness Incident Report) is more restrictive than the current recordkeeping requirement of completing OSHA Form 301 Injury and Illness Incident Report within 7 calendar days of the incident (1904.29(b)(3)). This modified, more stringent incident investigation and reporting requirement is restricted to intervention-related hyperbaric (recordable) incidents only. Providing rapid notification to OSHA is essential because time is a critical element in OSHA's ability to determine the continued effectiveness of the variance conditions in preventing hyperbaric incidents, and the applicant's identification and implementation of appropriate corrective and preventive actions.

Further, these notification requirements also enable the applicant, its employees, and OSHA to assess the effectiveness of the permanent variance in providing the requisite level of safety to the applicant's workers and based on this assessment, whether to revise or revoke the conditions of the permanent variance. Timely notification permits OSHA to take whatever action may be necessary and appropriate to prevent possible further injuries and illnesses. Providing notification to employees informs them of the precautions taken by the applicant to prevent similar incidents in the future.

Additionally, this condition requires the applicant to notify OSHA if it ceases to do business, has a new address or location for the main office, or transfers the operations covered by the permanent variance to a successor company. In addition, the condition specifies that the transfer of the permanent variance to a successor company must be approved by OSHA. These requirements allow OSHA to communicate effectively with the applicant regarding the status of the permanent variance and expedite the agency's administration and enforcement of the permanent variance. Stipulating that the applicant is required to have OSHA's approval to transfer a variance to a successor company provides assurance that the successor company has knowledge of, and will comply with, the conditions specified by the permanent variance, thereby ensuring the safety of workers involved in performing the operations covered by the permanent variance.

VII. Order

As of the effective date of this final order, OSHA is revoking the interim order granted to the employer on March 27, 2024 (89 FR 21274) and replacing it with a permanent variance order. Note that there are not any substantive changes in the conditions between the interim order and this final order.

OSHA issues this final order authorizing Ballard to comply with the following conditions instead of complying with the requirements of 29 CFR 1926.803 (f)(1), (g)(1)(iii), and (g)(1)(xvii). These conditions are:

A. Scope

The permanent variance applies only when Ballard stops the tunnel-boring work, pressurizes the working chamber, and the CAWs either enter the working chamber to perform an intervention (*i.e.*, inspect, maintain, or repair the mechanical-excavation components), or exit the working chamber after performing interventions.

The permanent variance applies only to work:

1. That occurs in conjunction with construction of the Lower Olentangy Tunnel Project, a tunnel constructed using advanced shielded mechanical-excavation techniques and involving operation of a TBM;
2. In the TBM's forward section (the working chamber) and associated hyperbaric chambers used to pressurize and decompress employees entering and exiting the working chamber; and
3. Performed in compliance with all applicable provisions of 29 CFR part 1926 except for the requirements specified by 29 CFR 1926.803 (f)(1), (g)(1)(iii), and (g)(1)(xvii).
4. This order will remain in effect until one of the following conditions occurs: (1) completion of the Lower Olentangy Tunnel Project; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

B. List of Abbreviations

Abbreviations used throughout this permanent variance includes the following:

1. CAW—Compressed-air worker
2. CFR—Code of Federal Regulations
3. DCI—Decompression Illness
4. DMT—Diver Medical Technician
5. TBM—Earth Pressure Balanced Micro-Tunnel Boring Machine
6. HOM—Hyperbaric Operations Manual
7. JHA—Job hazard analysis
8. OSHA—Occupational Safety and Health Administration
9. OTPCA—Office of Technical Programs and Coordination Activities

C. Definitions

The following definitions apply to this permanent variance, Ballard's project-specific HOM, and all work carried out under the conditions of this permanent variance.

1. *Affected employee or worker*—an employee or worker who is affected by the conditions of this permanent variance, or any one of his or her authorized representatives. The term "employee" has the meaning defined and used under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*).

2. *Atmospheric pressure*—the pressure of air at sea level, generally 14.7 pounds per square inch absolute (p.s.i.a.), 1 atmosphere absolute, or 0 pounds per square inch gauge (p.s.i.g.).

3. *Compressed-air worker*—an individual who is specially trained and medically qualified to perform work in a pressurized environment while breathing air at pressures not exceeding 27 p.s.i.g.

4. *Competent person*—an individual who is capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.¹²

5. *Decompression illness*—an illness (also called decompression sickness or "the bends") caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure. Examples of symptoms of decompression illness include, but are not limited to: joint pain (also known as the "bends" for agonizing pain or the "niggles" for slight pain); areas of bone destruction (termed dysbaric osteonecrosis); skin disorders (such as cutis marmorata, which causes a pink marbling of the skin, or in people with darker skin tones, the rash will appear as a marbled or lacy dark brown or purplish color); spinal cord and brain disorders (such as stroke, paralysis, paresthesia, and bladder dysfunction); cardiopulmonary disorders, such as shortness of breath; and arterial gas embolism (gas bubbles in the arteries that block blood flow).¹³

Note: Health effects associated with hyperbaric intervention, but not considered symptoms of DCI, can include: barotrauma (direct damage to air-containing cavities in the body such as ears, sinuses, and lungs);

¹² Adapted from 29 CFR 1926.32(f).

¹³ See Appendix 10 of "A Guide to the Work in Compressed-Air Regulations 1996," published by the United Kingdom Health and Safety Executive available from NIOSH at <http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-254/compReg1996.pdf>.

nitrogen narcosis (reversible alteration in consciousness that may occur in hyperbaric environments and is caused by the anesthetic effect of certain gases at high pressure); and oxygen toxicity (a central nervous system condition resulting from the harmful effects of breathing molecular oxygen (O₂) at elevated partial pressures).

6. *Diver Medical Technician*—Member of the dive team who is experienced in first aid.

7. *Earth Pressure Balanced Tunnel Boring Machine*—the machinery used to excavate a tunnel.

8. *Hot work*—any activity performed in a hazardous location that may introduce an ignition source into a potentially flammable atmosphere.¹⁴

9. *Hyperbaric*—at a higher pressure than atmospheric pressure.

10. *Hyperbaric intervention*—a term that describes the process of stopping the TBM and preparing and executing work under hyperbaric pressure in the working chamber for the purpose of inspecting, replacing, or repairing cutting tools and/or the cutterhead structure.

11. *Hyperbaric Operations Manual*—a detailed, project-specific health and safety plan developed and implemented by Ballard for working in compressed air during the Lower Olentangy Tunnel Project.

12. *Job hazard analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.

13. *Man-lock*—an enclosed space capable of pressurization, and used for compressing or decompressing any employee or material when either is passing into, or out of, a working chamber.

14. *Medical Advisor*—medical professional experienced in the physical requirements of compressed air work and the treatment of decompression illness.

15. *Pressure*—a force acting on a unit area. Usually expressed as pounds per square inch (p.s.i.).

16. *p.s.i.*—pounds per square inch, a common unit of measurement of pressure; a pressure given in p.s.i. corresponds to absolute pressure.

17. *p.s.i.a.*—pounds per square inch absolute, or absolute pressure, is the sum of the atmospheric pressure and gauge pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a. Adding 14.7 to a pressure expressed in units of p.s.i.g. will yield the absolute pressure, expressed as p.s.i.a.

18. *p.s.i.g.*—pounds per square inch gauge, a common unit of pressure;

pressure expressed as p.s.i.g. corresponds to pressure relative to atmospheric pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a. Subtracting 14.7 from a pressure expressed in units of p.s.i.a. yields the gauge pressure, expressed as p.s.i.g. At sea level the gauge pressure is 0 p.s.i.g.

19. *Qualified person*—an individual who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.¹⁵

20. *Working chamber*—an enclosed space in the TBM in which CAWs perform interventions, and which is accessible only through a man-lock.

D. Safety and Health Practices

1. Ballard must implement the project-specific HOM submitted to OSHA as part of the application (see OSHA-2024-0003-0003). The HOM provides the minimum requirements regarding expected safety and health hazards (including anticipated geological conditions) and hyperbaric exposures during the tunnel-construction project.

2. Ballard must demonstrate that the TBM on the project is designed, fabricated, inspected, tested, marked, and stamped in accordance with the requirements of ASME PVHO-1.2019 (or most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*) for the TBM's hyperbaric chambers.

3. Ballard must implement the safety and health instructions included in the manufacturer's operations manuals for the TBM, and the safety and health instructions provided by the manufacturer for the operation of decompression equipment.

4. Ballard must ensure that there are no exposures to pressures greater than 27 p.s.i.g.

5. Ballard must ensure that air or oxygen is the only breathing gas in the working chamber.

6. Ballard must follow the 1992 French Decompression Tables for air or oxygen decompression as specified in the HOM; specifically, the extracted portions of the 1992 French Decompression tables titled, "French Regulation Air Standard Tables."

7. Ballard must equip man-locks used by employees with an air or oxygen delivery system, as specified by the HOM for the project. Ballard is

prohibited from storing in the tunnel any oxygen or other compressed gases used in conjunction with hyperbaric work.

8. Workers performing hot work under hyperbaric conditions must use flame-retardant personal protective equipment and clothing.

9. In hyperbaric work areas, Ballard must maintain an adequate fire-suppression system approved for hyperbaric work areas.

10. Ballard must develop and implement one or more job hazard analysis (JHA) for work in the hyperbaric work areas, and review, periodically and as necessary (e.g., after making changes to a planned intervention that affects its operation), the contents of the JHAs with affected employees. The JHAs must include all the job functions that the risk assessment indicates are essential to prevent injury or illness.

11. Ballard must develop a set of checklists to guide compressed-air work and ensure that employees follow the procedures required by the permanent variance (including all procedures required by the HOM approved by OSHA for the project, which this permanent variance incorporates by reference). The checklists must include all steps and equipment functions that the risk assessment indicates are essential to prevent injury or illness during compressed-air work.

12. Ballard must ensure that the safety and health provisions of this project-specific HOM adequately protect the workers of all contractors and subcontractors involved in hyperbaric operations for the project to which the HOM applies.

E. Communication

1. Prior to beginning a shift, Ballard must implement a system that informs workers exposed to hyperbaric conditions of any hazardous occurrences or conditions that might affect their safety, including hyperbaric incidents, gas releases, equipment failures, earth or rockslides, cave-ins, flooding, fires, or explosions.

2. Ballard must provide a power-assisted means of communication among affected workers and support personnel in hyperbaric conditions where unassisted voice communication is inadequate.

(a) Ballard must use an independent power supply for powered communication systems, and these systems have to operate such that use or disruption of any one phone or signal location will not disrupt the operation of the system from any other location.

¹⁴ Also see 29 CFR 1910.146(b).

¹⁵ Adapted from 29 CFR 1926.32(m).

(b) Ballard must test communication systems at the start of each shift and as necessary thereafter to ensure proper operation.

F. Worker Qualifications and Training

Ballard must:

1. Ensure that each affected worker receives effective training on how to safely enter, work in, exit from, and undertake emergency evacuation or rescue from, hyperbaric conditions, and document this training.

2. Provide effective instruction on hyperbaric conditions, before beginning hyperbaric operations, to each worker who performs work, or controls the exposure of others, and document this instruction. The instruction must include:

(a) The physics and physiology of hyperbaric work;

(b) Recognition of pressure-related injuries;

(c) Information on the causes and recognition of the signs and symptoms associated with decompression illness, and other hyperbaric intervention-related health effects (e.g., barotrauma, nitrogen narcosis, and oxygen toxicity);

(d) How to avoid discomfort during compression and decompression;

(e) Information the workers can use to contact the appropriate healthcare professionals should the workers have concerns that they may be experiencing adverse health effects from hyperbaric exposure; and

(f) Procedures and requirements applicable to the employee in the project-specific HOM.

3. Repeat the instruction specified in paragraph (G) of this condition periodically and as necessary (e.g., after making changes to its hyperbaric operations).

4. When conducting training for its hyperbaric workers, make this training available to OSHA personnel and notify the OTPCA at OSHA's national office and OSHA's Columbus, Ohio Area Office before the training takes place.

G. Inspections, Tests, and Accident Prevention

1. Ballard must initiate and maintain a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems (such as temperature control, illumination, ventilation, and fire-prevention and fire-suppression systems), and hyperbaric work areas, as required under 29 CFR 1926.20(b)(2), including:

(a) Developing a set of checklists to be used by a competent person in conducting weekly inspections of hyperbaric equipment and work areas; and

(b) Ensuring that a competent person conducts daily visual checks and weekly inspections of the TBM.

2. Ballard must remove any equipment that is found to constitute a safety hazard until Ballard corrects the hazardous condition and has the correction approved by a qualified person.

3. Ballard must maintain records of all tests and inspections of the TBM, as well as associated corrective actions and repairs, at the job site for the duration of the tunneling project and for 90 days after the final project report is submitted to OSHA.

H. Compression and Decompression

Ballard must consult with its attending physician concerning the need for special compression or decompression exposures appropriate for CAWs not acclimated to hyperbaric exposure.

I. Recordkeeping

In addition to completing OSHA Form 301 Injury and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, Ballard must maintain records of:

1. The date, times (e.g., time compression started, time spent compressing, time performing intervention, time spent decompressing), and pressure for each hyperbaric intervention.

2. The names of all supervisors and DMTs involved for each intervention.

3. The name of each individual worker exposed to hyperbaric pressure and the decompression protocols and results for each worker.

4. The total number of interventions and the amount of hyperbaric work time at each pressure.

5. The results of the post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity or other health effects associated with work in compressed air for each hyperbaric intervention.

J. Notifications

1. To assist OSHA in administering the conditions specified herein, Ballard must:

(a) Notify the OTPCA and the OSHA Area Office in Columbus, Ohio at www.osha.gov/contactus/byoffice of any recordable injury, illness, or fatality (by submitting the completed OSHA Form 301 Injury and Illness Incident Report)¹⁶ resulting from exposure of an

employee to hyperbaric conditions, including those that do not require recompression treatment (e.g., nitrogen narcosis, oxygen toxicity, barotrauma), but still meet the recordable injury or illness criteria of 29 CFR 1904. The notification must be made within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, or fatality; a copy of the incident investigation (OSHA Form 301 Injuries and Illness Incident Report) must be submitted to OSHA within 24 hours of the incident or 24 hours after becoming aware of a recordable injury, illness, or fatality. In addition to the information required by OSHA Form 301 Injuries and Illness Incident Report, the incident-investigation report must include a root-cause determination, and the preventive and corrective actions identified and implemented.

(b) Provide certification to OTPCA and the OSHA Area Office in Columbus, Ohio within 15 working days of the incident that Ballard informed affected workers of the incident and the results of the incident investigation (including the root-cause determination and preventive and corrective actions identified and implemented).

(c) Notify the OTPCA and the OSHA Area Office in Columbus, Ohio within 15 working days and in writing, of any change in the compressed-air operations that affects Ballard's ability to comply with the conditions specified herein.

(d) Upon completion of the Lower Olentangy Tunnel Project, evaluate the effectiveness of the decompression tables used throughout the project, and provide a written report of this evaluation to the OTPCA and the OSHA Area Office in Columbus, Ohio.

Note: The evaluation report must contain summaries of: (1) The number, dates, durations, and pressures of the hyperbaric interventions completed; (2) decompression protocols implemented (including composition of gas mixtures (air and/or oxygen), and the results achieved; (3) the total number of interventions and the number of hyperbaric incidents (decompression illnesses and/or health effects associated with hyperbaric interventions as recorded on OSHA Form 301 Injuries and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, and relevant medical diagnoses, and treating physicians' opinions); and (4) root causes of any hyperbaric incidents, and preventive and corrective actions identified and implemented.

(e) To assist OSHA in administering the conditions specified herein, inform the OTPCA and the OSHA Area Office

¹⁶ See 29 CFR 1904 (Recording and Reporting Occupational Injuries and Illnesses) (http://www.osha.gov/pls/oshaweb/owadisp.show_

[document?p_table=STANDARDS&p_id=9631](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631)); recordkeeping forms and instructions <https://www.osha.gov/recordkeeping/forms>.

in Columbus, Ohio as soon as possible, but no later than seven (7) days, after it has knowledge that it will:

- (i) Cease doing business;
- (ii) Change the location and address of the main office for managing the tunneling operations specified herein; or
- (iii) Transfer the operations specified herein to a successor company.

(f) Notify all affected employees of this permanent variance by the same means required to inform them of its application for a permanent variance.

2. This permanent variance cannot be transferred to a successor company without OSHA approval.

OSHA hereby grants a permanent variance to Ballard Marine Construction for the

completion of the Lower Olentangy Tunnel Project in Columbus, Ohio.

VIII. Authority and Signature

Douglas L. Parker, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 655(d), Secretary of Labor's Order No. 8–2020 (85 FR 58393, Sept. 18, 2020), and 29 CFR 1905.11.

Signed at Washington, DC, on September 3, 2024.

Douglas L. Parker,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–22002 Filed 9–25–24; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL SCIENCE FOUNDATION

Networking and Information Technology Research and Development Request for Information on a National Plan for Cyber-Physical Systems Resilience

AGENCY: Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO), National Science Foundation.

ACTION: Request for information.

SUMMARY: On behalf of Office of Science and Technology Policy (OSTP), the NITRD National Coordination Office seeks public input for the creation of a National Plan for Cyber-Physical Systems Resilience Research (the Plan). The goal of the plan is to shape a whole-of-government research and development (R&D) plan related to cyber-physical resilience across systems that may be local, regional, or national in scope. As defined in the President's

Council of Advisors on Science and Technology (PCAST) Report, *Strategy for Cyber-Physical Resilience: Fortifying Our Critical Infrastructure for a Digital World*, cyber-physical systems are defined as physical systems that rely on computing technologies for sensing, analysis, tracking, controls, connectivity, coordination, and human-system interaction. The *National Climate Resilience Framework* defines resilience as the ability to prepare for threats and hazards, adapt to changing conditions, and withstand and recover rapidly from adverse conditions and disruptions. From the perspective of the RFI, the system recovery period and performance are acceptable from a social and technical perspective. These definitions will be used for the purposes of this RFI, but respondents are welcome to provide alternate definitions if cyber-physical systems have a different meaning in their industry or field, along with the scientific rationale for specific use-cases. The Plan is scheduled to be released in 2025.

DATES: Interested persons are invited to submit comments on or before 11:59 p.m. (ET) on October 26, 2024.

ADDRESSES: Comments submitted in response to this RFI may be sent by any of the following methods:

- **Email:** CPSR-ftacRFI@nitr.gov; Email submissions should be machine-readable and not be copy-protected. Submissions should include “RFI Response: Cyber-Physical Systems Resilience R&D Plan” in the subject line of the message.
- **Mail:** Attn: Melissa Cornelius, 2415 Eisenhower Avenue, Alexandria, VA 22314, USA.

Instructions: Response to this RFI is voluntary. Each individual or institution is requested to submit only one response. Submissions must not exceed 10 pages in 12 point or larger font, with a page number provided on each page. Responses must include the name of the person(s) or organization(s) filing the comment and the following statement: “This document is approved for public dissemination. The document contains no business-proprietary or confidential information. Document contents may be reused by the government in the National Cyber-Physical Systems Resilience R&D Strategic Plan and associated documents without attribution.”

Responses to this RFI may be posted online at <https://www.nitr.gov/>. Therefore, we request that no business proprietary information, copyrighted information, or sensitive personally identifiable information be submitted as part of your response to this RFI.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI.

FOR FURTHER INFORMATION CONTACT:

David Alexander, David Corman, Kristin Ludwig, Melissa Cornelius, Martin Stanley at CPSR-ftacRFI@nitr.gov or (202) 459–9674. Individuals who use a telecommunications device 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 time, Monday through Friday, except for U.S. Federal Government holidays.

SUPPLEMENTARY INFORMATION: The (PCAST) released its report, *Strategy for Cyber-Physical Resilience: Fortifying our Critical Infrastructure for a Digital World*. The report makes recommendations to formulate a National Plan for Cyber-Physical Resilience Research. The goal is to enable focused research across Federal programs that increase the likelihood of successful research results, but more importantly help ensure that such results will transition into practice. In response to this, the Fast-Track Action Committee (FTAC) on Cyber-Physical Systems Resilience (CPSR) is developing a National Cyber Physical Systems Resilience (R&D) Strategic Plan (the Plan) which will define research needs that will strengthen our national capability to cyber-physical resilience; identify the gaps; and define research needs, and investment priorities spanning across multiple time horizons. The Plan will coordinate cross-agencies priorities. Responsible innovation in cyber physical resilience could provide significant benefits for the American people especially as systems need to adapt to emergent behaviors or operating conditions far exceeding design specifications.

Information Requested: This RFI seeks input to shape a whole-of-government effort on research and development that will strengthen cyber-physical resilience.

In the context of this RFI, we refer to threats to include cybersecurity, physical, natural disasters including extreme weather events or other hazards such as earthquakes, and the potential for adversary use of AI to disrupt systems as well as deceive human operators of critical infrastructure systems.

Threat-agnostic approaches for resilience are of special interest. As part of the input, we are primarily concerned with the ability of cyber-physical

systems to recover and adapt while ability to withstand may be already covered in the current risk assessment and management efforts. We are particularly interested in how resilience by design or resilience by intervention can prepare for recovery and adaptation in different threat scenarios as well as in threat-agnostic situations.

Examples of domains and application of interest include but are not limited to critical infrastructure and systems for energy, transportation, medical, agriculture, water, space, manufacturing, and other R&D topic areas in which the strategic plan should focus, as well as details that should be considered when/if the topic area is elaborated in the strategic plan.

This RFI is NOT soliciting approaches solely focused on risk assessment and management through shielding cyber-physical systems from specific threats including threat identification and sensing, or through hardening the system to make it less vulnerable to specific threat or disruptions. Submitters are encouraged to address the topics of this RFI clearly and concisely.

References

- PCAST Releases Report on Strategy for Cyber-Physical Resilience (<https://www.whitehouse.gov/pcast/briefing-room/2024/02/27/pcast-releases-report-on-strategy-for-cyber-physical-resilience/>), The White House, February 2024.
- National Climate Resilience Framework (<https://www.whitehouse.gov/wp-content/uploads/2023/09/National-Climate-Resilience-Framework-FINAL.pdf> <https://www.whitehouse.gov/wp-content/uploads/2023/09/National-Climate-Resilience-Framework-FINAL.pdf>).
- Strategy for Cyber-Physical Resilience: Fortifying Our Critical Infrastructure for a Digital World, (https://www.whitehouse.gov/wp-content/uploads/2024/02/PCAST_Cyber-Physical-Resilience-Report_Feb2024.pdf) Executive Office of the President, President's Council of Advisors on Science and Technology, February 2024.
- Cyber-Physical Systems Resilience—The Networking and Information Technology Research and Development (NITRD) Program (<https://www.nitrd.gov/coordination-areas/cyber-physical-systems-resilience/>).
- Submitted by the National Science Foundation in support of the Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) on September

20, 2024.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2024–22005 Filed 9–25–24; 8:45 am]

BILLING CODE 7555–01–P

NEIGHBORHOOD REINVESTMENT CORPORATION

Sunshine Act Meetings

TIME AND DATE: 3:30 p.m., Monday, September 30, 2024.

PLACE: via ZOOM.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Special Board of Directors meeting.

The General Counsel of the Corporation has certified that in her opinion, one or more of the exemptions set forth in the Government in the Sunshine Act, 5 U.S.C. 552b(c)(2) permit closure of the following portion(s) of this meeting:

- Executive (Closed) Session

Agenda

- Call to Order
- Approval of Government in Sunshine Act Notice Waiver for a Meeting of the Board of Directors
- Sunshine Act Approval of Executive (Closed) Session
- Executive Session: Special Topic
- Discussion Item: Overview of Strategic Planning Process & Discussion Questions
- Discussion Item: Key Themes from Market Research and Internal Scan
- Discussion Item: Emerging Strategic Focus Areas
- Next Steps

PORTIONS OPEN TO THE PUBLIC: Everything except the Executive (Closed) Session.

PORTIONS CLOSED TO THE PUBLIC: Executive (Closed) Session.

CONTACT PERSON FOR MORE INFORMATION: Jenna Sylvester, Paralegal, (202) 568–2560; jsylvester@nw.org.

Jenna Sylvester,
Paralegal.

[FR Doc. 2024–22183 Filed 9–24–24; 11:15 am]

BILLING CODE 7570–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2024–0166]

NRC Implementation of the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of public meetings.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is implementing the requirements in the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (the ADVANCE Act, or the Act). The NRC plans to hold public meetings periodically to support the NRC's implementation of the ADVANCE Act.

DATES: This document was published in the **Federal Register** on September 26, 2024. Public meetings will be noticed in the NRC's Public Meeting Notice System at least 10 days in advance of the scheduled meeting. The NRC will not issue a separate **Federal Register** notice each time a public meeting is scheduled.

FOR FURTHER INFORMATION CONTACT:

Shilp Vasavada, Office of the Executive Director for Operations, telephone: 301–415–1228; email: Shilp.Vasavada@nrc.gov; or Aaron McCraw, Office of the Executive Director for Operations, telephone: 630–829–9650; email: Aaron.McCraw@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information

You may obtain publicly available information related to the NRC's implementation of the ADVANCE Act by any of the following methods:

- **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.

- **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.

II. Background

The ADVANCE Act was signed into law by President Biden on July 9, 2024. The Act, which can be found at <https://www.congress.gov/118/bills/s870/BILLS-118s870enr.pdf>, contains a variety of requirements relevant to the NRC. They address a wide range of NRC activities, such as the NRC's budgeting process, recruitment and retention of the NRC workforce, reduced fee rates for advanced nuclear reactor applicants and pre-applicants, the regulatory framework for advanced reactors and fusion technology, as well as strategies to enhance the NRC's efficient, timely, and predictable reviews of license applications. The Act also requires the NRC to provide reports to Congress on various topics. The NRC has initiated implementation of the Act and will be taking additional actions to carry out the Act's provisions, including requirements with deadlines over the course of the next few years.

III. Discussion

The ADVANCE Act requires the NRC to take a number of actions while maintaining the NRC's core mission to protect public health and safety and promote the common defense and security. The NRC is undertaking multiple actions to implement the requirements of the ADVANCE Act and meet the Act's various deadlines. The NRC will periodically hold public meetings on the NRC's efforts to implement the ADVANCE Act. The NRC may make preliminary material, such as white papers, available to support stakeholder engagement during public meetings. If preliminary material is released to support a public meeting on ADVANCE Act implementation, information about the preliminary material will be included in the corresponding public meeting notice. The information discussed at the public meetings and any preliminary material made publicly available may be incomplete in one or more respects; however, the NRC welcomes diverse stakeholder feedback to inform its efforts to implement the ADVANCE Act.

Public meetings to support the NRC's implementation of the ADVANCE Act will be noticed in the NRC's Public Meeting Notice System at least 10 days in advance of the scheduled meeting. The NRC will not issue a **Federal Register** notice each time a public meeting is scheduled. Please monitor the public web page.

Feedback on the NRC's implementation of the ADVANCE Act can also be provided via the publicly available feedback form on the NRC's ADVANCE Act website at <https://www.nrc.gov/about-nrc/governing-laws/advance-act/contactus.html>, or via email through ADVANCE-Act.Resource@nrc.gov. The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your submission provided through this feedback form or email address. The NRC will enter the 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.

Submissions received will be considered as part of the NRC's implementation of the ADVANCE Act, and whether the NRC responds to the submission may depend on the nature of the question or comment. Submissions may be used or modified by the NRC in the NRC's implementation of the ADVANCE Act without attribution to the author of the submission.

Dated: September 23, 2024.

For the Nuclear Regulatory Commission.

Michael King,

Special Assistant to the Executive Director for Operations, Office of the Executive Director for Operations.

[FR Doc. 2024-22052 Filed 9-25-24; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2024-0151]

Draft Interim Staff Guidance: Contamination Control, Radiological Survey, and Dose Modeling Considerations To Support License Termination at Sites With Environmental Discrete Radioactive Particle Contamination

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is soliciting public comment on its draft Interim Staff Guidance (ISG), DUWP-ISG-03, "Draft Interim Staff Guidance on Contamination Control, Radiological Survey, and Dose Modeling Considerations to Support License Termination at Sites with Environmental Discrete Radioactive Particle Contamination." The draft ISG addresses contamination control, radiological surveys, and dose modeling regarding discrete radioactive particles (DRPs) that are found in the environment due to an unplanned release or that potentially could be released to the environment during decommissioning. If finalized, this ISG would allow staff to develop consistent guidance regarding contamination control, particularly focused on non-diffuse contamination, during the decommissioning process, as well as provide acceptable survey approaches and dose methods for discrete radioactive particles until the appropriate NRC regulatory guidance can be updated.

DATES: Submit comments by October 28, 2024. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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-2024-0151. 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:

Amy M. Snyder, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone:

301-415-6822; email: Amy.Snyder@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2024-0151 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-2024-0151.
- *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. The draft ISG is available in ADAMS under Accession No. ML24219A032.

- *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.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC-2024-0151 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

Current decommissioning guidance is focused on addressing diffuse residual radioactivity with respect to performing surveys and assessing potential public exposure after license termination and does not address discrete radioactive particle contamination nor discuss how to control this type of contamination during decommissioning. For these reasons, the NRC staff have approached each past instance of DRP contamination on a case-by-case basis which may have led to some perceived inconsistencies in the approach to decommissioning. This draft guidance presents an acceptable approach for addressing discrete radioactive particle contamination throughout the decommissioning process. Such non-diffuse contamination can be found at power reactors, as well as fuel cycle facilities during any phase of decommissioning.

The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML24227A987).

III. Backfitting, Forward Fitting, and Issue Finality

Issuance of this ISG, if finalized, would not (i) constitute backfitting as defined in section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), "Backfitting," 70.76, "Backfitting," and 72.62, "Backfitting," and as described in Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests"; or (ii) affect issue finality of any approval issued under 10 CFR part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"; or (iii) constitute forward fitting as that term is defined and described in MD 8.4, because licensees would not be required to comply with the positions set forth in this ISG, if finalized.

Dated: September 20, 2024.

For the Nuclear Regulatory Commission.

Jane Marshall,

Director, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2024-22003 Filed 9-25-24; 8:45 am]

BILLING CODE 7590-01-P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Historical Pension Plan Tracing Service Intake Information

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act, of a new collection of information. The purpose of the information collection is to obtain information that the Office of the PBGC Participant and Plan Sponsor Advocate requires from the public to conduct its pension plan tracing service. This notice informs the public of PBGC's request and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before October 28, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

All comments received will be posted without change to PBGC's website, www.pbgc.gov, including any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information.

A copy of the request will be posted on PBGC's website at <https://www.pbgc.gov/prac/laws-and-regulation/federal-register-notices-open-for-comment>. It may also be obtained without charge by writing to the Disclosure Division (disclosure@pbgc.gov), Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024-2101; or, calling 202-229-4040 during normal business hours. If you are deaf or hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

FOR FURTHER INFORMATION CONTACT:

Monica O'Donnell (odonnell.monica@pbgc.gov), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024-2101, 202-229-8706. If you are deaf or hard of hearing, or have a speech

disability, please dial 7-1-1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: The Office of the PBGC Participant and Plan Sponsor Advocate (OPPSA) acts as a liaison between PBGC, sponsors of defined benefit pension plans insured by PBGC, and participants in pension plans trustee by PBGC. OPPSA assists participants with searching for historical pension plan information as part of its pension plan tracing service. To conduct the tracing research, OPPSA uses an internal pension plan tracing research dashboard, which displays select data elements from various PBGC systems, including annual premium filing records and case information. The information found through OPPSA's tracing research can help participants locate historical plan information.

To perform the search, OPPSA will request participant contact information and specific plan information. This information includes the participant's name, phone number, email address, and the inquirer's name and relationship to participant if the inquirer is not the participant; the employer's name and location; the pension plan name; the employer identification number (EIN); the plan number (PN); the years that the participant worked for the employer; whether the person was an hourly, salaried, or part-time employee; and any additional information about the employer or pension plan that would aid in plan tracing, including listing any documents the participant has related to the pension plan. The collection of information is voluntary and minimally burdensome. It will enable OPPSA to more effectively run its pension plan tracing service and to assist participants in locating historical plan information.

On July 22, 2024, PBGC published in the **Federal Register** (at 89 FR 59172) a notice informing the public of its intent to request approval of this collection of information. No comments were received. PBGC is requesting that OMB approve the collection of information for 3 years. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PBGC estimates that it will receive intake information from approximately 200 participants annually and that it will take participants 0.5 hours to complete and submit the information. The time needed to provide the information will vary among participants depending on what information they have readily available to them. The total amount of burden

associated with this collection of information is estimated to be 100 hours and an estimated \$0.

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2024-22110 Filed 9-25-24; 8:45 am]

BILLING CODE 7709-02-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-029, OMB Control No. 3235-0037]

Proposed Collection; Comment Request; Extension: Rule 17f-1(c) and Form X-17F-1A

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information provided for in Rule 17f-1(c) (17 CFR 240.17f-1(c) and Form X-17F-1A (17 CFR 249.100) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Rule 17f-1(c) requires approximately 9,500 entities in the securities industry to report lost, stolen, missing, or counterfeit securities certificates to the Commission or its designee, to a registered transfer agent for the issue, and, when criminal activity is suspected, to the Federal Bureau of Investigation. Such entities are required to use Form X-17F-1A to make such reports. Filing these reports fulfills a statutory requirement that reporting institutions report and inquire about missing, lost, counterfeit, or stolen securities. Since these reports are compiled in a central database, the rule facilitates reporting institutions to access the database that stores information for the Lost and Stolen Securities Program ("Program").

We estimate that the total reporting burden for Regulation 17f-1(c), as adopted, for all respondents is approximately 2,937.5 hours. These burdens consist of a one-time burden in connection with Accenture Federal Services LLC ("Accenture") becoming the new Program operator of

approximately 2,000 hours for set-up, and annual burdens thereafter of approximately 25 hours for maintenance and 287.5 hours for reporting. [2,000 + 3(25 + 287.5) = 2,937.5 hours]

- The Commission estimates that approximately 50 reporting institutions will be subject to this one-time burden, which corresponds to 40 hours for each of the applicable reporting institutions. Further, the Commission estimates that updates in the applicable reporting institutions' systems to maintain this connectivity will impose an aggregate ongoing annualized burden of 25 burden hours, which corresponds to 30 minutes for each of the applicable reporting institutions. Accordingly, this estimated burden to establish and maintain connectivity with Accenture over three years results in an aggregate burden of 691.67 hours per year or 13.83 hours per applicable reporting institution per year. [(50 Respondents × 1 Responses over 3 years) = 50 × (40 hour) = 2,000 hours/3 years = 666.67 hours per year; (50 Respondents × 1 Responses) = 50 × (.5 hours) = 25 hours; 666.67 hours + 25 hours = 691.67 hours; 691.67 hours/50 Respondents = 13.83 hours/Respondent].

- In addition, we estimate that approximately 115 reporting institutions will submit a report on average 30 times each year. The staff estimates that the average amount of time necessary for each reporting institution to comply with the Rule 17f-1(c) and Form X-17F-1A is five minutes. As a result, the total hourly burden for the periodic reporting burden under Rule 17f-1(c) is approximately 287.5 hours [(115 Respondents × 30 Responses) × (5 minutes/60 minutes/hour)].

Written comments are invited on: (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 estimates of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by November 25, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Oluwaseun Ajayi, 100 F Street NE, Washington, DC 20549, or send an email to: PRA_Mailbox@sec.gov.

Dated: September 23, 2024.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–22047 Filed 9–25–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101122; File No. SR–PEARL–2024–44]

Self-Regulatory Organizations; MIAx PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAx Pearl Options Fee Schedule

September 20, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on September 11, 2024, MIAx PEARL, LLC (“MIAx Pearl” or “Exchange”) filed with the Securities and Exchange Commission (“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

The Exchange is filing a proposal to amend the MIAx Pearl Options Fee Schedule (“Fee Schedule”).

The text of the proposed rule change is available on the Exchange’s website at <https://www.miaxglobal.com/markets/us-options/pearl-options/rule-filings> at MIAx Pearl’s principal office, 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 amend Section (1)(a) of the Fee Schedule, Exchange Rebates/Fees—Add/Remove Tiered Rebates/Fees, to: (1) amend the Priority Customer³ origin table to increase certain Maker rebates in Penny Classes (defined below); (2) establish a new “Step-Up Maker Rebate” (described below) for the MIAx Pearl⁴ Market Maker⁵ origin in Non-Penny Classes; and (3) remove certain alternative volume criteria and corresponding footnotes applicable to executions of orders for the Market Maker origin and non-Priority Customer, firm, broker-dealer (“BD”), and non-MIAx Pearl Market Maker origin (collectively referred to herein as “Professional Members”). The Exchange initially filed this proposal on August 30, 2024 (SR–PEARL–2024–39). On September 11, 2024, the Exchange withdrew SR–PEARL–2024–39 and refiled this proposal.

Background

The Exchange currently assesses transaction rebates and fees to all market participants which are based upon the total monthly volume executed by the Member⁶ on MIAx Pearl in the relevant, respective origin

type (not including Excluded Contracts)⁷ (as the numerator) expressed as a percentage of (divided by) TCV⁸ (as the denominator). In addition, the per contract transaction rebates and fees are applied retroactively to all eligible volume for that origin type once the respective threshold tier has been reached by the Member. The Exchange aggregates the volume of Members and their Affiliates.⁹ Members that place resting

⁷ The term “Excluded Contracts” means any contracts routed to an away market for execution. See the Definitions section of the Fee Schedule.

⁸ The term “TCV” means total consolidated volume calculated as the total national volume in those classes listed on MIAx Pearl for the month for which the fees apply, excluding consolidated volume executed during the period time in which the Exchange experiences an “Exchange System Disruption” (solely in the option classes of the affected Matching Engine (as defined below)). See the Definitions section of the Fee Schedule. The term “Exchange System Disruption” means an outage of a Matching Engine or collective Matching Engines for a period of two consecutive hours or more, during trading hours. *Id.* A “Matching Engine” is a part of the MIAx Pearl electronic system that processes options orders and trades on a symbol-by-symbol basis. Some Matching Engines will process option classes with multiple root symbols, and other Matching Engines may be dedicated to one single option root symbol (for example, options on SPY may be processed by one single Matching Engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated Matching Engine. A particular root symbol may not be assigned to multiple Matching Engines. *Id.* The Exchange believes that it is reasonable and appropriate to select two consecutive hours as the amount of time necessary to constitute an Exchange System Disruption, as two hours equates to approximately 1.4% of available trading time per month. The Exchange notes that the term “Exchange System Disruption” and its meaning have no applicability outside of the Fee Schedule, as it is used solely for purposes of calculating volume for the threshold tiers in the Fee Schedule.

⁹ The term “Affiliate” means (i) an affiliate of a Member of at least 75% common ownership between the firms as reflected on each firm’s Form BD, Schedule A, or (ii) the Appointed Market Maker of an Appointed EEM (or, conversely, the Appointed EEM of an Appointed Market Maker). An “Appointed Market Maker” is a MIAx Pearl Market Maker (who does not otherwise have a corporate affiliation based upon common ownership with an EEM) that has been appointed by an EEM and an “Appointed EEM” is an EEM (who does not otherwise have a corporate affiliation based upon common ownership with a MIAx Pearl Market Maker) that has been appointed by a MIAx Pearl Market Maker, pursuant to the following process. A MIAx Pearl Market Maker appoints an EEM and an EEM appoints a MIAx Pearl Market Maker, for the purposes of the Fee Schedule, by each completing and sending an executed Volume Aggregation Request Form by email to membership@miaxoptions.com no later than 2 business days prior to the first business day of the month in which the designation is to become effective. Transmittal of a validly completed and executed form to the Exchange along with the Exchange’s acknowledgement of the effective designation to each of the Market Maker and EEM will be viewed as acceptance of the appointment. The Exchange will only recognize one designation per Member. A Member may make a designation not more than once every 12 months (from the date

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ The term “Priority Customer” means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). The number of orders shall be counted in accordance with Interpretation and Policy .01 of Exchange Rule 100. See the Definitions section of the Fee Schedule and Exchange Rule 100, including Interpretation and Policy .01.

⁴ All references in this filing to “MIAx Pearl” are to the options trading facility of MIAx PEARL, LLC. Any references to the equities trading facility of MIAx PEARL, LLC would be to “MIAx Pearl Equities.” See Exchange Rule 1901.

⁵ The term “Market Maker” means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of Exchange Rules. See the Definitions section of the Fee Schedule and Exchange Rule 100.

⁶ The term “Member” means an individual or organization that is registered with the Exchange pursuant to Chapter II of Exchange Rules for purposes of trading on the Exchange as an “Electronic Exchange Member” or “Market Maker.” Members are deemed “members” under the Exchange Act. See the Definitions section of the Fee Schedule and Exchange Rule 100.

liquidity, *i.e.*, orders resting on the Book¹⁰ of the MIAx Pearl System,¹¹ are paid the specified “maker” rebate (each a “Maker”), and Members that execute against resting liquidity are assessed the specified “taker” fee (each a “Taker”). For opening transactions and ABBO¹² uncrossing transactions, per contract transaction rebates and fees are waived for all market participants. Finally, Members are assessed lower transaction fees and receive lower rebates for order executions in standard option classes in the Penny Interval Program¹³ (“Penny Classes”) than for order executions in standard option classes which are not in the Penny Interval Program (“Non-Penny Classes”), where Members are assessed higher transaction fees and receive higher rebates.

Proposal To Amend the Priority Customer Origin Table To Increase Certain Maker Rebates in Penny Classes

First, the Exchange proposes to amend the Priority Customer origin table to increase the Maker rebates in tiers 1 and 2 for Priority Customer orders in Penny Classes that trade against all origins. Currently, the Priority Customer origin table provides certain volume criteria thresholds for all tiers that are based upon the total monthly volume executed in all option classes by a Priority Customer on MIAx Pearl as a percentage of TCV. Pursuant to the Priority Customer origin table, Priority Customers qualify for the following Maker rebates when Priority Customer orders in Penny Classes trade against all origins: (i) (\$0.25)¹⁴ per contract in tiers 1 and 2 if the Priority Customer executes above 0.00% to at least 0.40% of TCV; (ii) (\$0.45) per

of its most recent designation), which designation shall remain in effect unless or until the Exchange receives written notice submitted 2 business days prior to the first business day of the month from either Member indicating that the appointment has been terminated. Designations will become operative on the first business day of the effective month and may not be terminated prior to the end of the month. Execution data and reports will be provided to both parties. See the Definitions section of the Fee Schedule.

¹⁰ The term “Book” means the electronic book of buy and sell orders and quotes maintained by the System. See Exchange Rule 100.

¹¹ The term “System” means the automated trading system used by the Exchange for the trading of securities. See Exchange Rule 100.

¹² The term “ABBO” means the best bid(s) or offer(s) disseminated by other Eligible Exchanges (defined in Exchange Rule 1400(g)) and calculated by the Exchange based on market information received by the Exchange from OPRA. See the Definitions section of the Fee Schedule and Exchange Rule 100.

¹³ See Securities Exchange Act Release No. 88992 (June 2, 2020), 85 FR 35142 (June 8, 2020) (SR-PEARL-2020-06).

¹⁴ Rebates are denoted in parentheses in the Fee Schedule.

contract in tier 3 if the Priority Customer executes above 0.40% to at least 0.85% of TCV; (iii) (\$0.49) per contract in tier 4 if the Priority Customer executes above 0.85% to at least 1.25% of TCV; and (iv) (\$0.52) per contract in tiers 5 and 6 if the Priority Customer executes above 1.25% of TCV.

The Exchange now proposes to amend the Priority Customer origin table to increase the Maker rebates in tiers 1 and 2 from (\$0.25) to (\$0.31) per contract for Priority Customer orders in Penny Classes that trade against all origins. The Exchange does not propose to amend any of the volume threshold criteria or the Maker rebates or Taker fees in any other tier for Priority Customer orders. The purpose of this proposed change is for business and competitive reasons in order to attract additional Penny Class volume from Members by increasing the Maker rebates for options transactions in Penny Classes in tiers 1 and 2 for Priority Customer orders. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads.

Proposal To Establish the Step-Up Maker Rebate for Market Maker Orders in Non-Penny Classes

Next, the Exchange proposes to amend the Market Maker origin table to establish a new “Step-Up Maker Rebate,” which will be noted as footnote “(i)” following the table of transaction rebates and fees for the Market Maker origin in Section (1)(a) of the Fee Schedule. Currently, pursuant to the Market Maker origin table, Market Makers qualify for the following Maker rebates when Market Maker orders in Non-Penny Classes trade against all origins: (i) (\$0.30) per contract in tier 1 if the Market Maker executes above 0.00% to at least 0.20% of TCV; (ii) (\$0.30) per contract in tier 2 if the Market Maker executes above 0.20% to at least 0.50% of TCV, or satisfies one of the three alternative volume criteria of tier 2; ¹⁵ (iii) (\$0.60) per contract in

¹⁵ A Market Maker need only to satisfy one of the following three alternative volume criteria in order to receive the rebates or fees associated with tier 2 of the Market Maker origin table: (i) the total monthly volume executed by the Market Maker collectively in SPY/QQQ/IWM options on MIAx Pearl, not including Excluded Contracts, is above 0.55% of SPY/QQQ/IWM TCV; or (ii) the Market Maker adds liquidity collectively in SPY/QQQ/IWM options on MIAx Pearl, not including Excluded Contracts, above 0.30% of SPY/QQQ/IWM TCV; or (iii) the Market Maker satisfies the requirements of tier 2 of both the NBBO Setter Plus

tier 3 if the Market Maker executes above 0.50% to at least 0.85% of TCV, or satisfies the alternative volume criteria of tier 3; ¹⁶ (iv) (\$0.65) per contract in tier 4 if the Market Maker executes above 0.85% to at least 1.25% of TCV, or satisfies the alternative volume criteria of tier 4; ¹⁷ (v) (\$0.70) per contract in tier 5 if the Market Maker executes above 1.25% to at least 1.40% of TCV; and (vi) (\$0.85) per contract in tier 6 if the Market Maker executes above 1.40% of TCV.

The Exchange now proposes that a Market Maker may qualify for a Step-Up Maker Rebate of (\$0.86) per contract for Market Maker orders in Non-Penny Classes, instead of the otherwise applicable tiered Maker rebate described above for tiers 1 through 6. In order to receive the proposed Step-Up Maker Rebate, a Market Maker must have an increase in the percentage of their added liquidity in Non-Penny Classes, represented as a percentage of TCV, of at least 0.12% as compared to the

Program and tier 2 of the Midpoint Peg Order Adding Liquidity at the Midpoint Volume Tiers table (referred to herein as the “Midpoint Volume Tiers”) in the MIAx Pearl Equities Fee Schedule. MIAx Pearl Equities Fee Schedule, Sections (1)(c) and (1)(e) for a complete description of the volume requirements for tier 2 of the NBBO Setter Plus Program and tier 2 of the Midpoint Volume Tiers table. See also Securities Exchange Act Release No. 98956 (November 15, 2023), 88 FR 81125 (November 21, 2023) (SR-PEARL-2023-63) (providing more background and explanation of both programs for MIAx Pearl Equities); see also Fee Schedule, Section (1)(a), Market Maker origin table. The term “SPY/QQQ/IWM TCV” means total consolidated volume in SPY, QQQ, and IWM calculated as the total national volume in SPY, QQQ, and IWM for the month for which the fees apply, excluding consolidated volume executed during the period of time in which the Exchange experiences an Exchange System Disruption (solely in SPY, QQQ, or IWM options). See the Definitions section of the Fee Schedule.

¹⁶ Market Makers satisfy the alternative volume criteria of tier 3 by adding liquidity in SPY options on MIAx Pearl, not including Excluded Contracts, above 1.10% of SPY TCV. The term “SPY TCV” means total consolidated volume in SPY calculated as the total national volume in SPY for the month for which the fees apply, excluding consolidated volume executed during the period of time in which the Exchange experiences an Exchange System Disruption (solely in SPY options). See the Definitions section of the Fee Schedule. Further, Market Makers qualify for: (i) Maker rebates of (\$0.44) per contract in SPY, QQQ and IWM options for their Market Maker origin when trading against origins other than Priority Customer, and (ii) Maker rebates of (\$0.42) per contract in SPY, QQQ and IWM options for their Market Maker origin when trading against Priority Customer origins, if the Market Maker satisfies the alternative volume criteria of tier 3, described above, of at least 1.10% in SPY when adding liquidity. See Fee Schedule, Section (1)(a), note “♦”.

¹⁷ Market Makers satisfy the alternative volume criteria of tier 4 if the Market Maker’s executions solely in SPY options on MIAx Pearl, not including Excluded Contracts, is above 2.50% of SPY TCV.

Market Maker's July 2024¹⁸ added liquidity in Non-Penny Classes.

The Exchange proposes that the Step-Up Maker Rebate will expire no later than January 31, 2025 (referred to herein as the "sunset period"),¹⁹ which will be stated in the same proposed footnote "(i)" in the Fee Schedule. The Exchange will issue an alert to market participants should the Exchange determine that the Step-Up Maker Rebate will expire earlier than January 31, 2025 or if the Exchange determines to amend the criteria or rate applicable to the Step-Up Maker Rebate prior to the end of the sunset period, and file a corresponding rule filing pursuant to Rule 19b-4 of the Exchange Act with the Commission.

The proposed Step-Up Maker Rebate of (\$0.86) per contract is the same or within the range of similar rebates offered by competing options exchanges for transactions by market makers in Non-Penny Classes.²⁰ The Exchange notes at least two competing options exchanges provide similar calculations for enhanced rebates or reduced fees for certain types of market participant orders by utilizing a volume comparison of the current month to a prior baseline month.²¹ Accordingly, the proposed

¹⁸ The Exchange will use a baseline for added liquidity in Non-Penny Classes of 0.00% of TCV for market participants that become Market Makers of the Exchange after July 2024 for the purpose of the Step-Up Maker Rebate calculation.

¹⁹ The Exchange notes that at the end of the sunset period, the Step-Up Maker Rebate will no longer apply unless the Exchange files a rule filing pursuant to Rule 19b-4 of the Exchange Act with the Commission to amend the criteria terms or update the baseline month to a more recent month.

²⁰ See The Nasdaq Stock Market LLC ("Nasdaq"), Options 7 Pricing Schedule, Section 2, Nasdaq Options Market—Fees and Rebates, note 6, available at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rules/Nasdaq%20Options%207> (last visited August 21, 2024) (providing \$0.86 per contract rebate to market makers that add liquidity in non-penny classes for market makers that qualify for tier 6 for adding liquidity in penny classes); see also Choe BZX Exchange, Inc. ("BZX") Options Fee Schedule, Transaction Fees, Standard Rates table, available at https://www.choe.com/us/options/membership/fee_schedule/bzx/ (last visited August 21, 2024) (providing tiered rebates ranging from \$0.40 to \$0.88 per contract for market makers that add liquidity in non-penny classes).

²¹ See, e.g., Choe EDGX Exchange, Inc. ("EDGX") Options Fee Schedule, Footnotes, Market Maker Volume Tiers, Tier 2, available at https://www.choe.com/us/options/membership/fee_schedule/edgx/ (last visited August 21, 2024) (providing a reduced fee for a market maker that meets certain volume criteria, including a requirement that the market maker's step up average daily added volume in market maker orders from July 2019 is greater than or equal to 0.10% of their OCC customer volume); see also NYSE Arca, Inc. ("Arca") Options Fees and Charges, Trade-Related Charges for Standard Options, Customer Penny Posting Credit Tiers table, available at https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf (last visited August 21, 2024) (in general, providing enhanced rebate for a firm that

calculation for the Step-Up Maker Rebate is not a new or novel concept for the method in which to provide an enhanced rebate to market participants.

The purpose of this proposed change is to provide an incentive for Market Makers to provide liquidity in Non-Penny Classes in order to receive the enhanced Step-Up Maker Rebate of (\$0.86) per contract instead of the tiered rebate that would otherwise be applicable for such transactions. The Exchange believes that the proposed Step-Up Maker Rebate will encourage Market Makers to add more liquidity in Non-Penny Classes, thereby promoting price discovery and contributing to a deeper and more liquid market, which benefits all market participants and enhances the attractiveness of the Exchange as a trading venue. The purpose of including the proposed sunset period in the Fee Schedule is to provide clarity to Market Makers that, unless the Exchange determines to amend or otherwise modify the Step-Up Maker Rebate, the Step-Up Maker Rebate will expire at the end of the sunset period.

Proposal To Remove Certain Alternative Volume Criteria and Corresponding Footnotes

Next, the Exchange proposes to amend Section (1)(a) of the Fee Schedule to remove certain alternative volume criteria and corresponding footnotes applicable to executions of orders for the Market Maker and Professional Member origins.

The Exchange proposes to remove footnote "#" following the Market Maker origin table in Section (1)(a) of the Fee Schedule and the corresponding alternative volume criteria in tier 2 of the Market Maker origin table. As described above, the Exchange provides four alternative volume calculation methods pursuant to which a Market Maker may obtain the fees and rebates in tier 2 of the Market Maker origin table.²² The fourth volume calculation method in tier 2 of the Market Maker origin table is the cross-asset volume based requirement, denoted by footnote "#" following the Market Maker origin table, which requires Market Makers to satisfy the requirements of tier 2 of both the NBBO Setter Plus Program and tier 2 of the Midpoint Volume Tiers in the MIAX Pearl Equities Fee Schedule.²³

has an increase of at least 0.15% of TCADV in added liquidity over the firm's March 2020 level of added liquidity).

²² See, generally, Fee Schedule, Section (1)(a), Market Maker origin table. See also *supra* note 15.

²³ See MIAX Pearl Equities Fee Schedule, Sections (1)(c) and (1)(e) for a complete description of the volume requirements for tier 2 of the NBBO

The Exchange now proposes to remove the cross-asset volume calculation method and corresponding footnote "#" such that there will no longer be a cross-asset volume requirement for Market Makers to satisfy in order to reach the tier 2 rebates and fees of the Market Maker origin table. The Exchange does not propose to amend the other three alternative volume calculation methods that Market Makers can satisfy in order to reach the tier 2 rebates and fees of the Market Maker origin table.

The Exchange also proposes to remove footnote "***" and the corresponding alternative volume criteria following the table of fees and rebates for Market Maker orders and Professional Member orders in Section (1)(a) of the Fee Schedule. Footnote "***" provides that Market Makers and Professional Members may qualify for the Maker rebate and the Taker fee associated with the highest tier for transactions in Non-Penny Classes if the Market Maker or Professional Member executes more than 0.30% volume in Non-Penny Classes, not including Excluded Contracts, as compared to the TCV in all MIAX Pearl-listed option classes, in the respective origin (*i.e.*, either Market Maker origin or Professional Member origin). For purposes of qualifying for such rates, the Exchange aggregates the volume transacted by Members and their Affiliates in the following origin types in Non-Penny Classes: (1) MIAX Pearl Market Makers, and (2) non-Priority Customer, Firm, BD, and non-MIAX Pearl Market Makers, *i.e.*, Professional Members. The Exchange now proposes to remove footnote "***" and the corresponding alternative volume calculation method from the Fee Schedule.

The Exchange also proposes to remove footnote "^" and the corresponding alternative volume criteria following the table of fees and rebates for Professional Members in Section (1)(a) of the Fee Schedule. Footnote "^" provides that Professional Members may qualify for Maker rebates equal to the greater of: (A) (\$0.37) for Penny Classes and (\$0.65) for Non-Penny Classes, or (B) the amount set forth in the applicable tier reached by the Professional Member in the relevant origin, if the Member and their Affiliates execute at least 1.25% volume in the relevant month, in Priority Customer origin type, in all options classes, not

Setter Plus Program and tier 2 of the Midpoint Volume Tiers table. See also Securities Exchange Act Release No. 98956 (November 15, 2023), 88 FR 81125 (November 21, 2023) (SR-PEARL-2023-63) (providing more background and explanation of both programs for MIAX Pearl Equities).

including Excluded Contracts, as compared to the TCV in all MIAX Pearl listed option classes.

The purpose of these changes is for business and competitive reasons as well as to reduce complexity and provide clarity within the Fee Schedule. The Exchange initially established each of the above-described alternative volume calculations in order to attract Market Maker and/or Professional Member order flow. The Exchange recently conducted an internal review and analysis of fees and rebates and determined that it was appropriate to remove the alternative volume calculations described above. The Exchange's standard volume calculation methods (and the two alternative volume calculation methods for tier 2 of the Market Maker origin) remain highly competitive such that they should enable the Exchange to continue to attract Market Maker and Professional Member order flow and maintain market share. The Exchange also notes that no Member has recently achieved any of the three alternative volume calculation methods that the Exchange proposes to remove from the Fee Schedule; accordingly, the Exchange believes it will reduce complexity within the Fee Schedule and provide greater clarity to remove the alternative volume calculation methods that are not utilized.

Implementation

The proposed changes are immediately effective.

2. Statutory Basis

The Exchange believes that its proposal to amend the Fee Schedule is consistent with Section 6(b) of the Act²⁴ in general, and furthers the objectives of Section 6(b)(4) of the Act,²⁵ in that it is an equitable allocation of reasonable dues, fees and other charges among Exchange Members and issuers and other persons using its facilities, and 6(b)(5) of the Act,²⁶ 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 mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission has repeatedly expressed its preference for competition

over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."²⁷

There are currently 17 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange had more than approximately 14–15% of the multiply-listed equity options market share for the month of July 2024.²⁸ Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 3.45% of executed volume of multiply-listed equity options for the month of July 2024.²⁹

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can discontinue or reduce use of certain categories of products and services, terminate an existing membership or determine to not become a new member, and/or shift order flow, in response to transaction fee changes. For example, on February 28, 2019, the Exchange filed with the Commission a proposal to increase Taker fees in certain tiers for options transactions in certain Penny Classes for Priority Customers and decrease Maker rebates in certain tiers for options transactions in Penny Classes for Priority Customers (which fee was to be effective March 1, 2019).³⁰ The Exchange experienced a decrease in total market share for the month of March 2019, after the proposal went into effect. Accordingly, the Exchange believes that its March 1, 2019, fee change, to increase certain transaction fees and decrease certain transaction rebates, may have contributed to the decrease in MIAX Pearl's market share and, as such, the Exchange believes competitive forces constrain the Exchange's, and other options exchanges, ability to set transaction fees

and market participants can shift order flow based on fee changes instituted by the exchanges.

Proposal To Amend the Priority Customer Origin Table To Increase Certain Maker Rebates in Penny Classes

The Exchange believes its proposal to amend the Priority Customer origin to increase the Maker rebates in tiers 1 and 2 from (\$0.25) to (\$0.31) per contract for Priority Customer orders in Penny Classes that trade against all origins is reasonable, equitable and not unfairly discriminatory because it would further incentivize Priority Customer orders to the Exchange. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. The Exchange believes the proposed increased Maker rebates in tiers 1 and 2 for Priority Customer orders in Penny Classes is equitable and not unfairly discriminatory because it will apply equally to all market participants who provide Priority Customer orders in Penny Classes.

Proposal To Establish the Step-Up Maker Rebate for Market Maker Orders in Non-Penny Classes

The Exchange believes its proposal to establish the Step-Up Maker Rebate is reasonable, equitably allocated and not unfairly discriminatory because it provides Market Makers with an additional incentive to achieve a certain volume threshold on the Exchange in Non-Penny Classes. The Exchange believes that the proposed Step-Up Maker Rebate is reasonable because it may encourage Market Makers to add more liquidity in Non-Penny Classes, thereby promoting price discovery and contributing to a deeper and more liquid market, which benefits all market participants and enhances the attractiveness of the Exchange as a trading venue.

The Exchange believes that it is equitable and not unfairly discriminatory to provide the Step-Up Maker Rebate only to Market Maker orders because Market Makers have market-making obligations and regulatory requirements, which normally do not apply to other types of market participants, such as Professional Members.³¹ Market Makers additionally have obligations to make continuous markets, engage in a course of dealings reasonably calculated to

²⁷ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

²⁸ See the "Market Share" section of the Exchange's website, available at <https://www.miaxglobal.com/> (last visited August 22, 2024).

²⁹ See *id.*

³⁰ See Securities Exchange Act Release No. 85304 (March 13, 2019), 84 FR 10144 (March 19, 2019) (SR-PEARL-2019-07).

³¹ See, generally, Chapter VI of the Exchange's Rules.

²⁴ 15 U.S.C. 78f(b).

²⁵ 15 U.S.C. 78f(b)(4).

²⁶ 15 U.S.C. 78f(b)(1) and (b)(5).

contribute to the maintenance of a fair and orderly market, and not make bids or offers or enter into transactions that are inconsistent with a course of dealings. The Exchange believes the proposed Step-Up Maker Rebate is equitable and not unfairly discriminatory because it will be available equally to all Market Makers and will be provided in an equal manner to all Market Makers that satisfy the volume threshold requirements of the Step-Up Maker Rebate.

The proposed Step-Up Maker Rebate promotes just and equitable principles of trade, fosters cooperation and coordination with persons engaged in facilitating transactions in securities, and protects investors and the public interest because the proposed Step-Up Maker Rebate may encourage Market Makers to send more orders to the Exchange in Non-Penny Classes, which are typically less liquid as compared to Penny Classes. To the extent that Market Maker order flow in Non-Penny classes is increased by the proposal, market participants may increasingly compete for the opportunity to trade on the Exchange, including sending more orders which will have the potential to be assessed lower fees and higher rebates. The resulting increased volume and liquidity in Non-Penny Classes may benefit all Exchange participants by providing more trading opportunities and tighter spreads in option classes that are typically less liquid.

Additionally, the Exchange believes the proposed Step-Up Maker Rebate of (\$0.86) per contract is reasonable because it is the same, or within the range, of similar rebates offered by competing options exchanges for transactions by market makers in Non-Penny Classes.³² Also, the proposed calculation of the Step-Up Maker Rebate is reasonable and not unfairly discriminatory because it is similar to the calculation method utilized by at least two competing options exchanges that provide enhanced rebates or reduced fees for certain types of market participant orders by taking a volume comparison of the current month to a prior baseline month.³³ Accordingly, this approach to determining an enhanced rebate (or reduced fee) is not new or novel.

The Exchange believes that it is reasonable to include the sunset period in the Fee Schedule to provide clarity to all Market Makers that, unless the Exchange determines to amend or otherwise modify the Step-Up Maker

Rebate, the Step-Up Maker Rebate will expire at the end of the sunset period.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to use a baseline for added liquidity in Non-Penny Classes of 0.00% of TCV for market participants that become Market Makers of the Exchange after July 2024 for the purpose of the Step-Up Maker Rebate calculation because it will provide an additional incentive for prospective firms to become Market Makers. The Exchange believes this will incentivize new Market Makers to trade on the Exchange, which will add to price discovery, enhance liquidity and market quality, and contribute to a more robust and well-balanced market ecosystem on the Exchange to the benefit of all Members and market participants. The Exchange notes that the proposed Step-Up Maker Rebate will not adversely impact any Market Maker's ability to qualify for reduced fees or enhanced rebates offered under other pricing tiers/incentives on the Exchange. Should a Market Maker not meet the required criteria of the Step-Up Maker Rebate, the Market Maker will merely not receive the corresponding enhanced rebate.

Proposal To Remove Certain Alternative Volume Criteria and Corresponding Footnotes

The Exchange believes its proposal to remove the alternative volume criteria and corresponding footnotes described above that are applicable to executions of orders for the Market Maker and Professional Member origins is reasonable, equitably allocated and not unfairly discriminatory. The Exchange initially established each of the above alternative volume criteria in order to attract Market Maker and Professional Member order flow. The Exchange recently conducted an internal review and analysis of fees and rebates and determined that it was reasonable, equitable and not unfairly discriminatory to remove the alternative volume calculations described above. The Exchange believes its standard volume calculation methods (and the two remaining alternative volume calculation methods for tier 2 of the Marker Maker origin) remain highly competitive such that they should enable the Exchange to continue to attract Market Maker and Professional Member order flow and maintain market share.

The Exchange believes these proposed changes are equitable and not unfairly discriminatory because no Member has recently achieved any of the three alternative volume calculation methods

that the Exchange proposes to remove from the Fee Schedule. As such, no Member will currently be impacted by the removal of these alternative volume calculation methods. The Exchange further believes that the removal of these alternative volume calculations will reduce complexity within the Fee Schedule and provide greater clarity to all Members, particularly since these methods are not utilized. Less complexity and greater clarity in the Fee Schedule helps promote just and equitable principles of trade and removes impediments to and perfects the mechanisms of a free and open market and a national market system.

The Exchange also believes it is equitable and not unfairly discriminatory to remove the alternative volume criteria described above because with the proposed changes, the Exchange's standard volume criteria (and the two remaining alternative volume calculation methods for tier 2 of the Marker Maker origin) will continue to apply equally to all Market Maker and Professional Member order flow, in each origin respectively.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that any of the proposed changes will impose any burden on intra-market competition.

Proposal To Amend the Priority Customer Origin Table To Increase Certain Maker Rebates in Penny Classes

The Exchange believes its proposal to amend the Priority Customer origin to increase the Maker rebates in tiers 1 and 2 from (\$0.25) to (\$0.31) per contract for Priority Customer orders in Penny Classes that trade against all origins will not impose any burden on intra-market competition. Instead, the Exchange believes this proposed change will promote competition because it will further incentivize Priority Customer orders to the Exchange. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads.

³² See *supra* note 20.

³³ See *supra* note 21.

Proposal To Establish the Step-Up Maker Rebate for Market Maker Orders in Non-Penny Classes

The Exchange believes its proposal to establish the Step-Up Maker Rebate will not impose any burden on intra-market competition because it provides all Market Makers with an additional incentive to achieve a certain volume threshold on the Exchange in Non-Penny Classes. The Exchange believes that this may encourage Market Makers to add more liquidity in Non-Penny Classes, thereby promoting price discovery and contributing to a deeper and more liquid market, which benefits all market participants and enhances the attractiveness of the Exchange as a trading venue. Again, the Exchange believes that this proposed change promotes competition to the benefit of all market participants on the Exchange, particularly in Non-Penny Classes, which are traditionally less liquid. The resulting increased volume and liquidity in Non-Penny Classes may benefit all Exchange participants by providing more trading opportunities and tighter spreads in option classes that are typically less liquid.

The Exchange also believes that using a baseline for added liquidity in Non-Penny Classes of 0.00% of TCV for market participants that become Market Makers of the Exchange after July 2024 for the purpose of the Step-Up Maker Rebate calculation will incentivize new market participants to trade on the Exchange and become Market Makers. In turn, this may add to price discovery, enhance liquidity and market quality, and contribute to a more robust and well-balanced market ecosystem on the Exchange to the benefit of all Members and market participants. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send additional orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. As described above, the opportunity to qualify for the proposed new Step-Up Maker Rebate will continue to be available to all Market Makers that meet the associated volume requirement. As such the Exchange does not believe the proposed changes would impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purpose of the Act.

Proposal To Remove Certain Footnotes and Alternative Volume Criteria

The Exchange believes its proposal to remove the alternative volume criteria and corresponding footnotes described

above that are applicable to executions of orders for the Market Maker and Professional Member origins will not impose any burden on intra-market competition. Each of these alternative volume criteria were established in order to attract Market Maker and Professional Member order flow. Based on the Exchange's recent internal review and analysis of fees and rebates, the Exchange believes its standard volume calculation methods (and the two remaining alternative volume calculation methods for tier 2 of the Market Maker origin) remain highly competitive such that they should enable the Exchange to continue to attract Market Maker and Professional Member order flow.

The Exchange believes these proposed changes do not impose any burden on intra-market competition because no Member has recently achieved any of the three alternative volume calculation methods that the Exchange proposes to remove from the Fee Schedule. As such, no Member will currently be impacted by the removal of these alternative volume calculation methods.

Inter-Market Competition

The Exchange does not believe that the proposed changes will impose any burden on inter-market competition and the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange had more than approximately 14–15% of the multiply-listed equity options market share for the month of July 2024.³⁴ Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 3.45% of executed volume of multiply-listed equity options for the month of July 2024.³⁵

In such an environment, the Exchange must continually adjust its rebates and tiers to remain competitive with other options exchanges. Because competitors are free to modify their own fees and tiers in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any

burden on competition is extremely limited. The Exchange believes that the proposed rule changes reflect this competitive environment because they modify the Exchange's tiers and rebates in a manner that encourages market participants to continue to provide liquidity and to send order flow to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,³⁶ and Rule 19b-4(f)(2)³⁷ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-PEARL-2024-44 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-PEARL-2024-44. 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

³⁴ See *supra* note 28.

³⁵ See *id.*

³⁶ 15 U.S.C. 78s(b)(3)(A)(ii).

³⁷ 17 CFR 240.19b-4(f)(2).

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-PEARL-2024-44 and should be submitted on or before October 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁸

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-22025 Filed 9-25-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101117; File No. SR-NYSE-2024-50]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt New Section 101.01 and Amend Section 103.00 of the NYSE Listed Company Manual To Explain the Application of the Domestic and International Standards for Initial Listing of Common Equity Securities for Foreign Private Issuers

September 20, 2024.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934

(“Act”)² and Rule 19b-4 thereunder,³ notice is hereby given that on September 10, 2024, New York Stock Exchange LLC (“NYSE” or the “Exchange”) 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt proposed new Section 101.01 of the NYSE Listed Company Manual to explain the application to foreign private issuers of the domestic and international standards for initial listing of common equity securities. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The minimum quantitative standards for the initial listing of common equity securities of domestic companies are set forth in Section 102.01 (“Minimum Numerical Standards—Domestic Companies—Equity Listings”) of the NYSE Listed Company Manual (the “Manual”). Section 103.01 (“Minimum Numerical Standards Non-U.S. Companies Equity Listings”) of the Manual sets forth minimum quantitative standards for the initial listing of common equity securities of foreign

private issuers.⁴ Notwithstanding the existence of separate listing standards for foreign private issuers, Section 103.00 of the Manual provides that foreign private issuers may list their common equity securities either under the quantitative standards for foreign private issuers set forth in Section 103.01 or the Exchange's domestic listing criteria set forth in Section 102.01. As stated in Section 103.00, the foreign private issuer must meet all of the criteria within the standards under which it qualifies for listing, but is not required to meet the requirements of both of those sections in order for its common equity securities to qualify for listing.

It has been the Exchange's experience in recent years that almost all foreign private issuer applicants whose common equity securities qualify for listing on the Exchange do so by meeting the domestic listing requirements of Section 102.01. However, the Exchange has become aware that there is a certain level of confusion in the marketplace about how to understand the listing standards as they apply to foreign private issuer applicants.

To provide greater clarity as to how the domestic and international listing standards relate to each other with regard to the listing of common equity securities, the Exchange proposes to adopt proposed new Section 101.01 (“Domestic and Foreign Private Issuer Quantitative Listing Standards”). As proposed, Section 101.01 would read as follows:

101.01 Domestic and Foreign Private Issuer Quantitative Listing Standards

Section 102.01 (“Minimum Numerical Standards—Domestic Companies—Equity Listings”) sets forth the minimum quantitative standards for the listing of common equity securities of domestic companies. In addition, the Exchange also lists applicants that are foreign private issuers (as defined in Section 103.00 (“Foreign Private Issuers”)) under Section 102.01 where such applicants are qualified for listing thereunder. However, if a foreign private issuer applicant does not meet all of the requirements for the listing of common equity securities applicable to domestic issuers under Section 102.01, the Exchange will determine whether such foreign private issuer qualifies for listing under the quantitative standards for common equity securities set forth in Section 103.01 (“Minimum Numerical Standards Non-U.S. Companies Equity Listings”). It is important

⁴ Section 103.00 (“Foreign Private Issuers”) provides that, for purposes of the Manual, the terms “foreign private issuer” and “non-U.S. company” have the same meaning and are defined in accordance with the SEC's definition of foreign private issuer set out in Rule 3b-4(c) of the Securities Exchange Act of 1934.

³⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

to note that a foreign private issuer applicant must meet all of the requirements for common equity securities of either Section 102.01 or Section 103.01 in their entirety but is not required to meet the requirements of both of Section 102.01 and Section 103.01 in order to qualify for listing. Foreign private issuers that list under either Section 102.01 or Section 103.01 will be subject to Section 103.00 and all of the subsections thereunder (except that foreign private issuers that list under Section 102.01 are not required to comply with Section 103.01), including Sections 103.02 (“Securities Exchange Act of 1934”), 103.03 (“Sponsorship by an Exchange Member Firm”) and 103.04 (“Sponsored American Depository Receipts or Shares (‘ADRs’)”). All listed foreign private issuers must also comply with the applicable corporate governance requirements set forth in Section 303A hereof.

The Exchange proposes to amend Section 103.00 to include a cross-reference to proposed Section 101.01 and to re-organize the text slightly without making any substantive changes by moving the sentence defining “foreign private issuer” and “non-U.S. company” into the first paragraph of the rule. The Exchange also proposes to replace current references throughout Section 103.00 to “Alternative Listing Standards” with references to “alternative listing standards,” as the capitalized term is not used as a defined term in that rule. In addition, the Exchange proposes to amend Section 103.00 to clarify that a foreign private issuer must meet all of the criteria for common equity securities of either Section 102.01 or Section 103.01 but is not required to meet the requirements of both of those sections in order for its common equity securities to qualify for listing. Finally, the Exchange proposes to add the following sentences to Section 103.00 to conform to proposed Section 101.01:

Foreign private issuers that list under either Section 102.01 or Section 103.01 will be subject to Section 103.00 and all of the subsections thereunder (except that foreign private issuers that list under Section 102.01 are not required to comply with Section 103.01), including Sections 103.02 (“Securities Exchange Act of 1934”), 103.03 (“Sponsorship by an Exchange Member Firm”) and 103.04 (“Sponsored American Depository Receipts or Shares (‘ADRs’)”). All listed foreign private issuers must also comply with the applicable corporate governance requirements set forth in Section 303A hereof.

The Exchange notes that the proposed amendments would not make any substantive change to the applicable initial listing standards. Their sole intended effect is to provide additional emphasis of the existing relationship between the domestic and international

listing standards as already articulated in Section 103.00.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁶ in particular, because 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 regulating, clearing, settling, processing information with respect to, and 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 and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange believes that the proposed rule change is consistent with the Act in that it does not make any substantive change to the rules as its sole purpose is to further investor protection by providing additional clarity with respect to the application of the existing quantitative initial listing standards that apply to foreign private issuers without making any substantive changes to the current rules.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.⁷

The Exchange believes that the proposal will not impose a burden on either intramarket or intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed simply to provide additional clarity and emphasis to the existing initial quantitative listing standards that apply to foreign private issuers without making any substantive changes to the current rules and, consequently, the Exchange believes that it will impose no burden on either intramarket or intermarket competition.

⁵ 15 U.S.C. 78f(b).

⁶ 15 U.S.C. 78f(b)(5).

⁷ 15 U.S.C. 78f(b)(8).

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act⁸ and Rule 19b-4(f)(6) thereunder.⁹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹⁰

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹¹ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<https://www.sec.gov/rules/sro.shtml>); or

⁸ 15 U.S.C. 78s(b)(3)(A)(iii).

⁹ 17 CFR 240.19b-4(f)(6).

¹⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has fulfilled this requirement.

¹¹ 15 U.S.C. 78s(b)(2)(B).

• Send an email to rule-comments@sec.gov. Please include file number SR–NYSE–2024–50 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–NYSE–2024–50. 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–NYSE–2024–50 and should be submitted on or before October 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024–22023 Filed 9–25–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101115; File No. SR–Phlx–2024–15]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Designation of Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change To Amend the Exchange's Fees for Top of PHLX Options (TOPO), PHLX Orders, and TOPO Plus Orders

September 20, 2024.

On March 20, 2024, Nasdaq PHLX LLC (“Phlx” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² a proposed rule change (File Number SR–Phlx–2024–15) to increase fees for certain market data products (“Proposal”). The proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.³ The proposed rule change was published for comment in the **Federal Register** on March 28, 2024.⁴ On May 16, 2024, the Commission issued an order temporarily suspending the proposed rule change pursuant to Section 19(b)(3)(C) of the Act⁵ and simultaneously instituting proceedings under Section 19(b)(2)(B) of the Act⁶ to determine whether to approve or disapprove the proposed rule change (“Order Instituting Proceedings”).⁷

Section 19(b)(2) of the Act⁸ provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A). A proposed rule change may take effect upon filing with the Commission if it is designated by the exchange as “establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization.” 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ See Securities Exchange Act Release No. 99841 (March 22, 2024), 89 FR 21648 (“Notice”).

⁵ 15 U.S.C. 78s(b)(3)(C).

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 100160, 89 FR 45036 (May 22, 2024). The Commission has received one comment letter on the proposed rule change, as well as a response from the Exchange to the Order Instituting Proceedings. Comments received on the Proposal are available at: <https://www.sec.gov/comments/sr-phlx-2024-15/srphlx202415.htm>.

⁸ 15 U.S.C. 78s(b)(2).

issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on March 28, 2024.⁹ September 24, 2024 is 180 days from that date, and November 23, 2024 is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and its comments. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,¹⁰ designates November 23, 2024 as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–Phlx–2024–15).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024–22021 Filed 9–25–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101116; File No. SR–ISE–2024–12]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Designation of Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Adopt Rules To List and Trade FLEX Options

September 20, 2024.

On March 11, 2024, Nasdaq ISE, LLC (“ISE” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² a proposed rule change to adopt rules that will govern the listing and trading of flexible exchange options (“FLEX Options”). The proposed rule change was published for comment in the **Federal Register** on March 29, 2024.³ On May 9, 2024, pursuant to

⁹ See Notice, *supra* note 4.

¹⁰ 15 U.S.C. 78s(b)(2).

¹¹ 17 CFR 200.30–3(a)(57).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 99825 (March 21, 2024), 89 FR 22294.

¹² 17 CFR 200.30–3(a)(12).

Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ On June 26, 2024, the Commission instituted proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act⁶ to determine whether to approve or disapprove the proposed rule change.⁷

Section 19(b)(2) of the Act⁸ provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of the notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on March 29, 2024.⁹ The 180th day after publication of the Notice is September 25, 2024. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,¹⁰ designates November 24, 2024 as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR-ISE-2024-12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-22019 Filed 9-25-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-421, OMB Control No. 3235-0481]

Proposed Collection; Comment Request; Extension: Rule 15c2-8

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (“PRA”) (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) is soliciting comments on the existing collection of information provided for in Rule 15c2-8 (17 CFR 240.15c2-8), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (“OMB”) for extension and approval.

Rule 15c2-8 requires broker-dealers to deliver preliminary and/or final prospectuses to certain people under certain circumstances. In connection with securities offerings generally, including initial public offerings (“IPOs”), the rule requires broker-dealers to take reasonable steps to distribute copies of the preliminary or final prospectus to anyone who makes a written request, as well as any broker-dealer who is expected to solicit purchases of the security and who makes a request. In connection with IPOs, the rule requires a broker-dealer to send a copy of the preliminary prospectus to any person who is expected to receive a confirmation of sale (generally, this means any person who is expected to actually purchase the security in the offering) at least 48 hours prior to the sending of such confirmation. This requirement is sometimes referred to as the “48-hour rule.”

Additionally, managing underwriters are required to take reasonable steps to ensure that all broker-dealers participating in the distribution of or trading in the security have sufficient copies of the preliminary or final prospectus, as requested by them, to

enable such broker-dealer to satisfy their respective prospectus delivery obligations pursuant to Rule 15c2-8, as well as Section 5 of the Securities Act of 1933.

Rule 15c2-8 implicitly requires that broker-dealers collect information, as such collection facilitates compliance with the rule. There is no requirement to submit collected information to the Commission. In order to comply with the rule, broker-dealers participating in a securities offering must keep accurate records of persons who have indicated interest in an IPO or requested a prospectus, so that they know to whom they must send a prospectus.

The Commission estimates that the time broker-dealers will spend complying with the collection of information required by the rule is 24,200 hours for equity IPOs and 23,970 hours for other offerings. The Commission estimates that the total annualized cost burden (copying and postage costs) is \$17,100,000 for IPOs and \$958,800 for other offerings.

Written comments are invited on: (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 estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by November 25, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Oluwaseun Ajayi, 100 F Street NE, Washington, DC 20549, or send an email to: PRA_Mailbox@sec.gov.

Dated: September 20, 2024.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-22014 Filed 9-25-24; 8:45 am]

BILLING CODE 8011-01-P

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 100086, 89 FR 42528 (May 15, 2024). The Commission designated June 27, 2024, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 100438, 89 FR 54886 (July 2, 2024) (Order Instituting Proceedings) (“OIP”).

⁸ 15 U.S.C. 78s(b)(2).

⁹ See Notice, *supra* note 3.

¹⁰ 15 U.S.C. 78s(b)(2).

¹¹ 17 CFR 200.30-3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101121; File No. SR–FINRA–2024–004]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving a Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend FINRA Rule 6730 (Transaction Reporting) To Reduce the 15-Minute TRACE Reporting Timeframe to One Minute

September 20, 2024.

I. Introduction

On January 11, 2024, the Financial Industry Regulatory Authority, Inc. (“FINRA”) filed with the Securities and Exchange Commission (“Commission” or “SEC”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder, ² a proposed rule change to amend FINRA Rule 6730 to reduce the 15-minute reporting timeframe for transactions reported to FINRA’s Trade Reporting and Compliance Engine (“TRACE”) system to one minute, with exceptions for FINRA members with de minimis reporting activity and for manual trades. The proposed rule change was published for comment in the **Federal Register** on January 25, 2024. ³ On February 29, 2024, the Commission extended until April 24, 2024, the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change. ⁴ On April 22, 2024, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change. ⁵ On July 18, 2024, the Commission, pursuant to Section 19(b)(2) of the Act, ⁶ designated September 20, 2024, as the date by which the Commission shall either approve or disapprove the proposed rule change. ⁷ Also on July 18, 2024, FINRA filed a partial amendment to the original proposal (“Partial Amendment No. 1”). On July 25, 2024, the Commission published notice of Partial

Amendment No. 1. ⁸ The Commission received comment letters in response to publications of the Notice, OIP, and Partial Amendment No. 1, ⁹ as well as a letter from FINRA. ¹⁰ This order approves the proposed rule change, as modified by Partial Amendment No. 1 (collectively, “Proposal”).

II. Description of the Proposed Rule Change

FINRA has collected and disseminated transaction information in fixed income securities through TRACE since 2002. ¹¹ FINRA rules currently specify the applicable outer-limit reporting timeframe for different types of TRACE-Eligible Securities. ¹² Most transactions ¹³ in corporate bonds, agency debt securities, ¹⁴ asset-backed securities (“ABS”), ¹⁵ and agency pass-through mortgage-backed securities (“MBS”) traded to-be-announced (“TBA”) for good delivery (“GD”) ¹⁶ must be reported within 15 minutes. The 15-minute reporting timeframe has been in place for corporate bonds since 2005, ¹⁷ and was implemented later for agency debt (2010), ¹⁸ ABS (2015), ¹⁹ and MBS TBA GD (2013). ²⁰ In 2015, the

Commission approved FINRA rule amendments requiring FINRA members to report transactions in these TRACE-Eligible Securities as soon as practicable but no later than 15 minutes from the time of execution, ²¹ and FINRA publicly disseminates information on these transactions immediately upon receipt. According to FINRA, “in 2022, 82.9 percent of the trades [in TRACE-Eligible Securities] executed after 8:00 a.m. and before 6:15 p.m. [Eastern Time (“ET”)] were reported within one minute of execution.” ²²

According to FINRA, “[s]ince the implementation of TRACE, the fixed income markets have changed dramatically, including a significant increase in the use of electronic trading platforms or other electronic communication protocols to facilitate the execution of transactions.” ²³ In light of these advances and consistent with FINRA’s goals of increasing transparency and improving access to timely transaction data, FINRA proposed updates to modernize the reporting timeframes and provide timelier transparency. ²⁴

A. One-Minute Reporting

FINRA proposed amendments to Rule 6730 to reduce the reporting timeframe for securities currently subject to the 15-minute reporting outer limit to one minute, with exceptions for FINRA member firms with de minimis reporting activity and for manual trades. FINRA would continue to make information on the transactions publicly available immediately upon receipt of the trade reports. ²⁵

Under existing Rule 6730(a)(1), transactions in corporate bonds, agency debt, ABS, and MBS TBA GD generally must be reported as soon as practicable, but no later than within 15 minutes of execution. ²⁶ Specifically, transactions executed on a business day at or after 12:00:00 a.m. ET through 7:59:59 a.m. ET must be reported the same day no later than 15 minutes after the TRACE system opens. Transactions executed on a business day at or after 8:00:00 a.m. ET through 6:29:59 p.m. ET must be reported no later than within 15 minutes of the Time of Execution, ²⁷

(Order Approving File No. SR–FINRA–2012–020); see also Regulatory Notice 12–26 (May 2012).

²¹ See Securities Exchange Act Release No. 75782 (August 28, 2015), 80 FR 53375 (September 3, 2015) (Order Approving File No. SR–FINRA 2015–025).

²² See Notice, 89 FR at Table 1.

²³ See *id.* at 5034.

²⁴ See *id.* at 5035.

²⁵ See *id.*

²⁶ See *supra* notes 17–21.

²⁷ Under Rule 6710(d), the “Time of Execution” generally means the time when the parties to a

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 99404 (January 19, 2024), 89 FR 5034 (January 25, 2024) (“Notice”).

⁴ See Securities Exchange Act Release No. 99640 (February 29, 2024), 89 FR 16042 (March 6, 2024).

⁵ See Securities Exchange Act Release No. 100006 (April 22, 2024), 89 FR 32475 (April 26, 2024) (“OIP”).

⁶ 15 U.S.C. 78s(b)(2).

⁷ See Securities Exchange Act Release No. 100555 (July 18, 2024), 89 FR 59948 (July 24, 2024).

⁸ See Securities Exchange Act Release No. 100594 (July 25, 2024), 89 FR 61514 (July 31, 2024) (“Partial Amendment No. 1”).

⁹ Comments received are available at: <https://www.sec.gov/comments/sr-fina-2024-004/srfinra2024004.htm>.

¹⁰ See Letter from Racquel L. Russell, Senior Vice President, Director of Capital Markets Policy, Office of General Counsel, FINRA, dated July 18, 2024, available at <https://www.sec.gov/comments/sr-fina-2024-004/srfinra2024004-491763-1411786.pdf> (“FINRA Letter”).

¹¹ See Securities Exchange Act Release No. 43873 (January 23, 2001), 66 FR 8131 (January 29, 2001) (Order Approving File No. SR–NASD–99–65).

¹² See FINRA Rule 6710(a) (providing a definition for “TRACE-Eligible Security”).

¹³ A “List or Fixed Offering Price Transaction,” as defined in Rule 6710(q), and a “Takedown Transaction,” as defined in Rule 6710(r) are required to be reported to TRACE by the next business day (T+1). See Rule 6730(a)(2).

¹⁴ See FINRA Rule 6710(l) (providing a definition for “Agency Debt Security”).

¹⁵ See FINRA Rule 6710(cc) (providing a definition for “Asset-Backed Security”).

¹⁶ See FINRA Rule 6710(v) (providing a definition for “Agency Pass-Through Mortgage-Backed Security”) and FINRA Rule 6710(u) (providing a definition for “To Be Announced”).

¹⁷ See Securities Exchange Act Release No. 49845 (June 14, 2004), 69 FR 35088 (June 23, 2004) (Order Approving File No. SR–NASD–2004–057); see also Notice to Members 04–51 (July 2004).

¹⁸ See Securities Exchange Act Release No. 60726 (September 28, 2009), 74 FR 50991 (October 2, 2009) (Order Approving File No. SR–FINRA–2009–010); see also Regulatory Notice 09–57 (September 2009).

¹⁹ See Securities Exchange Act Release No. 71607 (February 24, 2014), 79 FR 11481 (February 28, 2014) (Order Approving File No. SR–FINRA–2013–046); see also Regulatory Notice 14–34 (August 2014).

²⁰ See Securities Exchange Act Release No. 66829 (April 18, 2012), 77 FR 24748 (April 25, 2012)

except for transactions executed on a business day less than 15 minutes before 6:30 p.m. ET, which must be reported no later than 15 minutes after the TRACE system opens the next day (and, if reported on T+1, designated “as/of” with the date of execution). Finally, transactions executed on a business day at or after 6:30:00 p.m. ET through 11:59:59 p.m. ET, or trades executed on a Saturday, a Sunday, a federal or religious holiday, or other day on which the TRACE system is not open at any time during that day, must be reported on the next business day no later than 15 minutes after the TRACE system opens (and must be designated “as/of” and include the date of execution).

Amended Rule 6730(a)(1) would provide that transactions must be reported as soon as practicable, but no later than within one minute of the Time of Execution. Amended Rule 6730(a)(1)(A) would provide that transactions executed on a business day at or after 12:00:00 a.m. ET through 7:59:59 a.m. ET must be reported the same day as soon as practicable after the TRACE system opens, but no later than within 15 minutes after the TRACE system opens. Amended Rule 6730(a)(1)(B) would require that a transaction executed on a business day at or after 8:00:00 a.m. ET through 6:29:59 p.m. ET must be reported as soon as practicable, but no later than one minute from the Time of Execution, except that, a transaction executed on a business day less than one minute before 6:30:00 p.m. ET, must be reported no later than 15 minutes after the TRACE system opens the next business day (T+1) (and, if reported on T+1, designated “as/of” with the date of execution). Any trades executed on a business day prior to the open of the TRACE system, on a business day at or after 6:30:00 p.m. ET through 11:59:59 p.m. ET, or on a Saturday, a Sunday, a federal or religious holiday or other day on which the TRACE system is not open at any time during that day would continue to be reportable as soon as practicable on the next business day (T+1), but no later than within 15 minutes after the TRACE system opens (and must be designated “as/of,” as appropriate, and include the date of execution).

transaction agree to all of the terms of the transaction that are sufficient to calculate the dollar price of the trade. For transactions involving TRACE-Eligible Securities that are trading “when issued” on a yield basis, the “Time of Execution” is when the yield for the transaction has been agreed to by the parties to the transaction.

B. Exceptions From One-Minute Reporting

FINRA proposed two exceptions from the one-minute reporting timeframe for: (1) FINRA member firms with “limited trading activity” in the TRACE-Eligible Securities that are subject to one-minute reporting; and (2) manual trades.²⁸

1. Exception for FINRA Members With “Limited Trading Activity”

New Supplementary Material .08 would provide an exception to the one-minute reporting timeframe for FINRA members with “limited trading activity.” A FINRA member with “limited trading activity” would be defined as one that, during one of the prior two calendar years, reported to TRACE fewer than 4,000 transactions in the TRACE-Eligible Securities that are subject to paragraphs (a)(1)(A) through (a)(1)(D) of Rule 6730 (*i.e.*, corporate bonds, agency debt, ABS and MBS TBA GD), including any manual trades. Proposed Supplementary Material .08(b) would require FINRA members relying on the exception to confirm annually their qualification for the exception.²⁹ As outlined in proposed Supplementary Material .08(c), qualifying FINRA members would be required to report these trades as soon as practicable, but no later than within 15 minutes of the Time of Execution.³⁰

FINRA members exceeding the 4,000-trade threshold for each of two consecutive calendar years would need to comply with the one-minute reporting requirements of paragraphs (a)(1)(A) through (a)(1)(D) of the Rule beginning 90 days after the member no

²⁸ FINRA also proposed a conforming amendment to Supplementary Material .03 to refer to the Rule generally rather than “paragraph (a)” to reflect that FINRA members reporting pursuant to one of the exceptions in new Supplementary Material .08 and .09 are still required to report their trades “as soon as practicable.”

²⁹ Evidence of this confirmation should be retained as part of the FINRA member’s books and records. However, FINRA members eligible for the exception will not need to take other affirmative steps to have their trade reports processed pursuant to the exception’s 15-minute reporting timeframe, such as submitting a certification of eligibility to FINRA or adding a modifier or indicator to their trade reports. See Proposed FINRA Rule 6730 Supplementary Material .08(b).

³⁰ However, a trade executed at or after 12:00:00 a.m. through 7:59:59 a.m. ET would need to be reported as soon as practicable the same day, but no later than within 15 minutes after the TRACE system opens. Additionally, a trade executed on a business day at or after 6:30:00 p.m. through 11:59:59 p.m. ET; on a business day less than 15 minutes before 6:30 p.m. ET; or on a Saturday, Sunday, federal or religious holiday, or other day on which the TRACE system is not open at any time during that day, would need to be reported as soon as practicable, but no later than within 15 minutes after the TRACE system opens the next business day (T+1).

longer meets the criteria for the exception (*i.e.*, beginning 90 days after January 1 of the next calendar year). If a FINRA member’s reporting activity subsequently dropped below the 4,000-trade threshold, the FINRA member would again be eligible for the exception.³¹

2. Manual Trades Exception

New Supplementary Material .09 would provide an exception for manual trades that are not electronic from end to end. Where a trade qualifies for the manual trades exception, a 15-minute outer limit would apply for the first year following implementation; a 10-minute outer limit would apply for the second and third years; and a five-minute outer limit would apply thereafter.

The manual trades exception would apply to “transactions that are manually executed” or where a “[FINRA] member must manually enter any of the trade details or information necessary for reporting the trade through the TRAQS website or into a system that facilitates trade reporting to TRACE.”³² A trade that requires manual intervention at any point to complete the trade execution or reporting process would qualify.³³ According to FINRA,³⁴ it contemplates that the exception would be available for a variety of situations, including, for example:

- where a FINRA member executes a trade³⁵ by manual or hybrid means, such as by telephone, email, or through a chat/messaging function,³⁶ and

³¹ For example, a FINRA member that reported 3,000 trades in the relevant TRACE-Eligible Securities to TRACE in 2022 and then 4,150 trades in 2023 would continue to be eligible for the exception in 2024; however, if the FINRA member then reported 4,100 trades in 2024, the member would be required to comply with the one-minute reporting requirements starting 90 days after January 1, 2025 (with January 1 being day one of 90). If the FINRA member proceeded to report 3,500 trades in 2025, the member would once again be eligible for the exception from one-minute reporting for 2026 under the two-year lookback. FINRA states that it believes the two-year lookback period for eligibility for the exception will accommodate fluctuations in trading activity that may be due to unusual market-wide events or unique client demands. See Notice, 89 FR at 5036.

³² See Notice, 89 FR at 5036.

³³ See *id.*

³⁴ See *id.*

³⁵ As stated above, for purposes of Rule 6730, the reporting timeframe is measured from the Time of Execution as defined by Rule 6710(d), which generally refers to the time that the parties have agreed to all of the terms of the transaction sufficient to calculate the dollar price of the trade (or yield, in the case of when-issued securities priced to a spread). See Notice, 89 FR at n. 15.

³⁶ See Notice, 89 FR at 5036. FINRA reminds its members of their obligation to retain these electronic communications as part of their books and records, consistent with FINRA and SEC recordkeeping requirements. See, *e.g.*, Notice to Members 03–33 (July 2003).

subsequently must manually enter into a system that facilitates trade reporting all or some of the information required to book the trade and report it to TRACE (FINRA further explains “that, where the only manual step involved is to prompt the electronic execution of a trade (e.g., click ‘accept’), the manual trades exception would not be available”³⁷);³⁸

- where allocations to individual accounts must be manually input in connection with a trade by a dually-registered broker-dealer/investment adviser (FINRA states that if a block trade, allocated to individual accounts by a dually-registered broker-dealer/investment adviser, were “executed electronically without manual intervention between its execution and reporting, the manual trades exception would not be available for that separately executed block trade”³⁹);⁴⁰

- where an electronic trade is subject to manual review for risk management or regulatory compliance purposes and, as part of or following the review, the trade must be manually approved, amended, or released before the trade is reported to TRACE (e.g., a firm’s risk management procedures require a secondary approver for trades over a certain threshold; a firm’s best execution procedures require manually checking another market to confirm that a better price is not available to the customer) (FINRA explains that the exception “would not be available with regard to trades that are subject to automated compliance/risk checks but that are not selected for manual review/approval, or for trades that were subject to a pre-execution compliance or risk review, but that do not involve manual intervention between the time of execution and the trade report”⁴¹);⁴²

- where a FINRA member trades a bond for the first time and additional manual steps are necessary to set the bond up in the firm’s systems to book and report the trade (e.g., entering the CUSIP number and associated bond data into the firm’s system);⁴³ and

- where a FINRA member agrees to trade a basket of securities at a single price and manual action is required to calculate the price of component securities in the basket or to book and report the trade in component securities to TRACE (FINRA further states that “if manual action was not required to

calculate the price of component securities included in the basket or other steps necessary to book and report the trades to TRACE, then the manual trades exception would not be available”⁴⁴).⁴⁵

According to FINRA, the above examples are illustrative of the types of circumstances in which, due to the manual nature of components of the trade execution or reporting process, reporting a transaction within one minute of the Time of Execution may be unfeasible, even where a FINRA member makes reasonable efforts to report the trade as soon as practicable (as required). FINRA also states that it will assess FINRA members’ trade reporting in connection with manual trades to determine whether the five-minute trade reporting timeframe (to become applicable after three years)⁴⁶ is appropriate, and will be prepared to adjust, as necessary.⁴⁷

FINRA will review use of the manual trades exception. FINRA members may not, in any case, purposely delay the execution or reporting of a transaction by handling any aspect of a trade manually or introducing manual steps following the Time of Execution. Additionally, FINRA states that, considering the overarching obligation to report trades as soon as practicable, FINRA members should consider the types of transactions in which they regularly engage and whether they can reasonably reduce the time between a trade’s Time of Execution and its reporting, and more generally must make a good faith effort to report their trades as soon as practicable.⁴⁸

Under amended Rule 6730(d)(4), any FINRA member that executes or reports a trade manually would be required to append a manual trade indicator to the trade report. The indicator must be included in any manual trade, regardless of whether the FINRA member reports outside of the one-minute timeframe in reliance on the manual trades exception. FINRA states that application of the indicator would give FINRA important insight into manual trading and the use of the exception.⁴⁹ The indicator would not be included in publicly disseminated TRACE data.⁵⁰

Finally, FINRA proposed to amend Rule 6730(f) to provide that a pattern or practice of late reporting may be

considered conduct inconsistent with high standards of commercial honor and just and equitable principles of trade, in violation of Rule 2010, absent “reasonable justification” (in addition to the rule’s existing reference to “exceptional circumstances”).⁵¹ Recurring issues in the systems of a FINRA member firm or its vendor would not be considered a reasonable justification or exceptional circumstance that excuses a pattern or practice of late trade reporting.⁵²

III. Summary of Comments, FINRA’s Response, and Commission Findings

After carefully reviewing the Notice, Partial Amendment No. 1, and comment letters received, the Commission finds that the Proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.⁵³ In particular, the Commission finds that the Proposal is consistent with Section 15A(b)(6) of the Act,⁵⁴ which requires, among other things, that FINRA rules be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and 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; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Commission also finds that the Proposal is consistent, in particular, with Section 15A(b)(9) of the Act,⁵⁵ which requires that FINRA rules do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

In approving the original TRACE rules in 2002, the Commission stated that price transparency plays a fundamental role in promoting fairness and efficiency

⁵¹ See, e.g., Rule 6623 describing “exceptional circumstances” as instances of system failure by a FINRA member or service bureau, or unusual market conditions, such as extreme volatility in a security, or in the market as a whole.

⁵² See, e.g., FINRA Trade Reporting Frequently Asked Questions, Q206.21, available at <https://www.finra.org/filing-reporting/market-transparency-reporting/trade-reporting-faq>.

⁵³ In approving this proposed rule change, the Commission has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f); see also *infra* sections III.A (discussing the Proposal’s impact on efficiency of U.S. capital markets); and III.B and III.G (discussing comments and responses regarding the Proposal’s burden on competition).

⁵⁴ 15 U.S.C. 78o–3(b)(6).

⁵⁵ 15 U.S.C. 78o–3(b)(9).

³⁷ FINRA Letter at 9.

³⁸ See Notice, 89 FR at 5036.

³⁹ FINRA Letter at 8.

⁴⁰ See Notice, 89 FR at 5036.

⁴¹ FINRA Letter at 9.

⁴² See Notice, 89 FR at 5036.

⁴³ See *id.*

⁴⁴ FINRA Letter at 8.

⁴⁵ See Notice, 89 FR at 5036.

⁴⁶ FINRA Letter at 11.

⁴⁷ See Notice, 89 FR at 5036.

⁴⁸ See *id.*

⁴⁹ See *id.* at 5037.

⁵⁰ See *id.*

of U.S. capital markets.⁵⁶ Since 2002, FINRA has increased transparency by requiring more contemporaneous reporting and broadening the scope of securities included in TRACE. In 2005, FINRA shortened the deadline for reporting most transactions to TRACE to 15 minutes.⁵⁷ From 2010 through 2013, FINRA gradually expanded the classes of TRACE-eligible securities subject to reporting within 15 minutes.⁵⁸ In 2015, FINRA required FINRA member firms to report transactions in TRACE-Eligible Securities as soon as practicable but no later than within 15 minutes of the Time of Execution or other timeframe specified in FINRA Rule 6730.⁵⁹

A. One-Minute Reporting

The Commission received comments on the proposed rule change.⁶⁰ Several commenters support the proposal to shorten the 15-minute TRACE reporting timeframe to one minute and its aim of increasing transparency in the fixed income markets.⁶¹ Some commenters support increasing price transparency in general through reporting but caution restraint and the need for broad exceptions, citing the potential for reduced liquidity and execution quality.⁶² Some commenters oppose one minute reporting, questioning the feasibility and cost of compliance due to technical limitations and the prevalence of manual processes.⁶³ Some

commenters that oppose one minute reporting state that if the Commission moves forward with the adoption of the one minute reporting requirement, it should only do so in conjunction with the manual trades and de minimis exceptions.⁶⁴ Some commenters suggest FINRA withdraw the Proposal and instead require market participants to report trades as soon as practicable but no later than five minutes after execution.⁶⁵ One commenter also states that the one-minute reporting timeframe for electronic trades “will not meaningfully change the status quo for fully electronic trades,” as “FINRA acknowledges that the overwhelming majority of fully electronic transactions are already reported within one minute.”⁶⁶ Some commenters that oppose one minute reporting state FINRA did not sufficiently justify the need for the rule.⁶⁷ One commenter states that the Proposal “lack[s] evidence of a market failure to justify” the changes.⁶⁸ Another commenter states that Commission should reject the Proposal as amended by Partial Amendment No. 1.⁶⁹ This commenter

states that “FINRA and the Commission should improve the timeliness of TRACE reporting and dissemination,”⁷⁰ but also states that the manual trades exception “eviscerates any potentially added value from the ‘electronic’ provisions” and “encourages the return to ‘manual’ trading by those seeking to avoid transparency.”⁷¹

FINRA states that “approximately 83% of transactions in TRACE-eligible securities currently subject to the 15-minute reporting timeframe are reported within one minute of execution under requirements that, for some TRACE-eligible securities, have been in place for nearly 20 years, and FINRA believes it is appropriate and prudent to consider whether this timeframe continues to meet regulatory objectives given the passage of time and the changes in the fixed income securities industry in the intervening years.”⁷² Additionally, FINRA states that it believes that “identifying possible regulatory improvements need not be limited to instances where there has already been a market failure.”⁷³ FINRA further states that it continues to believe that the Proposal “represents an important step in modernizing the trade reporting timeframes for TRACE-eligible securities to facilitate more timely transaction data, enhancing transparency and the value of disseminated transaction data by allowing investors and other market participants to obtain and evaluate more timely pricing information for the impacted securities.”⁷⁴ Additionally, with respect to feasibility of one-minute reporting, especially with respect to fully electronic allocated trades, FINRA acknowledges this concern and describes its approach to enforcement of late reporting of transactions to TRACE under the Proposal by stating “that a pattern or practice of late reporting without reasonable justification may be considered conduct inconsistent with high standards of commercial honor and just and equitable principles of trade, in violation of Rule 2010,” but FINRA adds: “In considering whether ‘reasonable justification’ exists under proposed Rule 6730(f), FINRA will take into account factors such as the size and complexity of the trade, such as in the

⁵⁶ See *supra* note 11.

⁵⁷ See *supra* note 17.

⁵⁸ See *supra* notes 17–20.

⁵⁹ See *supra* note 21; see also <https://www.finra.org/rules-guidance/notices/15-41>.

⁶⁰ See *supra* note 9.

⁶¹ See, e.g., Letter from Stephen John Berger, Managing Director, Global Head of Government and Regulatory Policy, Citadel (February 15, 2024) (“Citadel Letter I”) at 1; Letter from Joanna Mallers, Executive Director, FIA Principal Traders Group (February 15, 2024) (“FIA PTG Letter”) at 1; Letter from Gerard O’Reilly, Co-Chief Executive Officer and Co-Chief Investment Officer, Dimensional Fund Advisors LP and David A. Plecha, Global Head of Fixed Income, Dimensional Fund Advisors LP (February 15, 2024) (“Dimensional Letter”) at 1; Letter from Ursula Baerlein (May 14, 2024); Letter from Dylan Parker, Chief Executive Officer, Moment Technology (May 15, 2024) (“Moment Technology Letter”) at 1.

⁶² See, e.g., Letter from Sarah A. Bessin, Deputy General Counsel, Investment Company Institute and Kevin Ercoline, Assistant General Counsel, Investment Company Institute (February 15, 2024) (“ICI Letter”) at 2; Letter from Frank Fairman, Managing Director, Piper Sandler (May 17, 2024) (“Piper Sandler Letter”) at 1.

⁶³ See, e.g., Letter from Kenneth E. Bentsen, Jr., President and CEO, Securities Industry and Financial Markets Association (February 15, 2024) (“SIFMA Letter I”) at 2; Letter from Kenneth E. Bentsen, Jr., President and CEO, Securities Industry and Financial Markets Association (May 17, 2024) (“SIFMA Letter II”) at 2 (suggesting transitioning to one-minute reporting would “expos[e] the broker-dealer community to significant regulatory risk and clients to diminished liquidity and service from their broker-dealers”); Letter from Christopher A.

Iacovella, President & Chief Executive Officer, American Securities Association (February 16, 2024) (“ASA Letter I”) at 2; Letter from Melissa P. Hoots, CEO/CCO, Falcon Square Capital (February 15, 2024) (“Falcon Letter I”) at 1–2; Letter from Melissa P. Hoots, CEO/CCO, Falcon Square Capital (August 21, 2024) (“Falcon Letter II”) at 2; Letter from Mark D. Griffin, SVP & Risk Control Manager, FHN Financial (May 17, 2024) (“FHN Letter”) at 2; LPL Letter at 1; Letter from Michael Decker, Senior Vice President, Bond Dealers of America (February 15, 2024) (“BDA Letter I”) at 2.

⁶⁴ See, e.g., SIFMA Letter I at 2; SIFMA Letter II at 2; FHN Letter at 2; BDA Letter I at 1; Letter from Michael Decker, Senior Vice President, Bond Dealers of America (May 17, 2024) (“BDA Letter II”) at 2; LPL Letter at 2.

⁶⁵ See Citadel at 4; FIA PTG at 4. *But cf.* SIFMA Letter II at 9 (stating that any alternative proposal that materially differs from the existing Proposal must be subject to notice and comment rulemaking and an economic analysis).

⁶⁶ Letter from Stephen John Berger, Managing Director, Global Head of Government & Regulatory Policy, Citadel (August 13, 2024) (“Citadel Letter II”) at 1.

⁶⁷ See, e.g., Falcon Letter I at 1; ASA Letter I at 2; Letter from Christopher A. Iacovella, President & Chief Executive Officer, American Securities Association (May 17, 2024) (“ASA Letter II”) at 1–2; Letter from Christopher A. Iacovella, President & Chief Executive Officer, American Securities Association (August 21, 2024) (“ASA Letter III”) at 1–2; FHN Letter at 2; SIFMA Letter II at 2.

⁶⁸ See ASA Letter I at 1; see also Falcon Letter II at 2 (“FINRA has still not substantiated the need for a reduction in reporting time for TRACE-eligible securities”).

⁶⁹ Letter from Tyler Gellasch, President and CEO, Healthy Markets Association (September 15, 2024) (“HMA Letter II”) at 1. This commenter states that it is writing to supplement its past support for shortening the TRACE reporting timeframe to more broadly object to the Proposal, citing, among other things, its prior comment letter on the Proposal. See *id.* (citing Letter from Tyler Gellasch, President and CEO, Healthy Markets Association (February 15, 2024) (“HMA Letter I”)).

⁷⁰ HMA Letter II at 3.

⁷¹ *Id.* at 1. This commenter also suggests changes to TRACE reporting protocols that are outside of the scope of the Proposal to provide for separate reports of information for price transparency and data useful to just regulators. See *id.* at 2.

⁷² FINRA Letter at 3.

⁷³ *Id.* at 3.

⁷⁴ *Id.* at 3–4.

case of allocation and portfolio trades.”⁷⁵

As discussed below, the Proposal is consistent with the Exchange Act. In particular, the Proposal will further increase price transparency by reducing the 15-minute TRACE reporting window to one minute while providing appropriately tailored exceptions for manual trades and FINRA members with de minimis reporting activity. The as soon as practicable but no later than 15-minute deadline for reporting trades by FINRA member firms with de minimis reporting activity, representing 1.41% of trades or 0.43% of the total par value traded, would remain unchanged.⁷⁶ FINRA states that the Proposal will likely result in at least an additional 5.3% of total trades reported within one minute.⁷⁷ FINRA additionally estimates that, “after adjusting for the proposed *de minimis* exception and prior to accounting for the manual exception, the Proposal could result in up to 16.4% of current annual trading volume, or up to 6.1 million trades and 20 trillion dollars in par value, being reported faster.”⁷⁸ Accordingly, the Commission views the Proposal as one that is reasonably designed to provide more timely trade reporting.

As the Commission has found previously, more timely reporting promotes fairness and efficiency of the U.S. capital markets.⁷⁹ Accordingly, the Commission finds that the Proposal will promote fair and orderly markets and protect investors and the public interest by increasing market transparency and providing the market with more timely pricing information, which may improve price efficiency. And as discussed below, FINRA responded to comments regarding the feasibility of complying with a one minute reporting requirement, including the feasibility and cost of compliance due to technical limitations and the prevalence of manual processes.⁸⁰ FINRA also responded to comments with respect to the feasibility of one-minute reporting for fully electronic allocated trades, for which FINRA provides data showing that 68% of allocated trades already were reported within one minute and 90.6% were reported within three

minutes,⁸¹ describes its approach to enforcement,⁸² and states that it will continue to study reporting times to determine if any regulatory changes are appropriate.⁸³ Moreover, FINRA responded to comments with respect to gamesmanship of the exceptions.⁸⁴ After carefully reviewing the Notice, Partial Amendment No. 1, and comment letters received, the Commission views the Proposal as reasonably balancing the benefits of more contemporaneous transaction reporting and transparency against the burden of requiring all transactions to be reported within one minute. Furthermore, the Commission agrees with FINRA that improving rules need not require a previous market failure.⁸⁵

B. General Comments on Exceptions to One-Minute Reporting

Commenters express varied views on the proposed exceptions to one minute reporting. Some commenters state the exceptions are essential to the success of the rule.⁸⁶ These commenters cite the burdens of compliance with one-minute reporting on broker-dealers that rely on manual processes.⁸⁷ Other commenters state that the exceptions are too narrow⁸⁸ or too broad.⁸⁹ One commenter states that for both exceptions, anything less than 15-minute reporting is infeasible and cites the issue that compliance costs associated with faster reporting could price small broker-dealers out of fixed

income markets.⁹⁰ One commenter that states the exceptions are too broad also states that the exceptions “create significant risk to the efficacy and legal durability of the entire rule.”⁹¹ This commenter also states that instead of improving market transparency the Proposal would “exacerbate, rather than reduce, information asymmetries.”⁹² One commenter encourages FINRA to phase out both exceptions completely over time, which it states would incentivize FINRA members to modernize their execution processes.⁹³ Another commenter states that both exceptions “complicate the rollout of the reporting compression process and unnecessarily deprive market participants of information necessary to achieve full market transparency,” and that “technological advances, particularly the use of APIs, make the need for these exceptions unnecessary and expensive relative the overall cost savings associated with transparency.”⁹⁴ Another commenter highlights that while 96.9% of non-ATS transactions are reported within five minutes, “[i]t is curious that the Proposal would sanction an outer reporting limit that is 3 times longer than the time it takes to report the overwhelming majority of ‘manual’ transactions today.”⁹⁵ The commenter states that this could contribute to undermining the transition to electronic trading in the fixed income markets.⁹⁶ Two commenters respond that commenters critical of the exceptions as proposed fail to recognize unique features of fixed income markets, such as the prevalence of manual trading and the heterogeneity of market participants, that make broad exceptions necessary.⁹⁷ One commenter also states that phasing out the *de minimis* exception, as suggested by another commenter, would drive small firms out of the fixed income business.⁹⁸

⁸¹ See FINRA Letter at 17 (citing Notice, 89 FR at 5034, 5041).

⁸² See *supra* note 75 and accompanying text.

⁸³ See FINRA Letter at 17.

⁸⁴ See *infra* notes 117 and 144 accompanying text.

⁸⁵ See *infra* section III.H (discussing that the Exchange Act does not require that a self-regulatory organization establish the existence of a market failure to justify a proposed rule change).

⁸⁶ See, e.g., BDA Letter I at 1; BDA Letter II at 2; Letter from Michael Decker, Senior Vice President, Research and Public Policy, Bond Dealers of America (August 21, 2024) (“BDA Letter III”) at 2; Letter from Howard Meyerson, Managing Director, Financial Information Forum (February 15, 2024) (“FIF Letter I”) at 2; Letter from Howard Meyerson, Managing Director, Financial Information Forum (May 17, 2024) (“FIF Letter III”) at 2; SIFMA Letter I at 3–4; SIFMA Letter II at 2; FHN Letter at 2; Piper Sandler Letter at 1 (stating that the Proposal “strike[s] an appropriate balance”).

⁸⁷ See BDA Letter I at 1; FIF Letter I at 2; FIF Letter III at 2; LPL Financial Letter at 1–2; SIFMA Letter I at 3–4; SIFMA Letter II at 2; see also BDA Letter II at 4 (stating small broker-dealers benefit fixed income markets and would be especially negatively affected by higher compliance costs associated with the Proposal).

⁸⁸ See, e.g., ASA Letter I at 1–2; Falcon Letter I at 1.

⁸⁹ See, e.g., Dimensional Letter at 2; HMA Letter II at I; HMA Letter I at 9–12; Citadel Letter I at 2–3; FIA PTC Letter at 1–2; Moment Technology Letter at 1.

⁹⁰ See ASA Letter I at 2; see also Falcon Letter I at 4 (“[O]ur fear is that the Filing will, over time, eliminate smaller fixed-income brokers”); Falcon Letter II at 1 (“Given the limits of [the *de minimis* and manual trades] exceptions, smaller broker-dealers like us risk being driven out of the fixed-income markets due to prohibitive costs.”); ASA Letter III at 2 (stating that the commenter’s concerns about the Proposal’s potential harm to market competition, particularly for smaller and mid-sized broker-dealers, remain unaddressed).

⁹¹ HMA Letter I at 2.

⁹² HMA Letter II at 3 (stating that the manual trades exception creates an opportunity to avoid transparency).

⁹³ See Dimensional Letter at 2.

⁹⁴ Moment Technology Letter at 2.

⁹⁵ Citadel Letter II at 2.

⁹⁶ *Id.*

⁹⁷ See BDA Letter II at 2–3; SIFMA Letter II at 8.

⁹⁸ See BDA Letter II at 4.

⁷⁵ FINRA Response Letter at 17.

⁷⁶ See Notice, 89 FR at 5043.

⁷⁷ See Notice, 89 FR at 5042.

⁷⁸ *Id.* at 4.

⁷⁹ See *supra* notes 56–59 and accompanying text.

⁸⁰ See *infra* sections III.C and III.D (discussing comments, and FINRA’s responses, on the *de minimis* and manual trades exceptions, including with respect to concerns regarding the feasibility of complying and the application of the rule in the context of manual trades).

With respect to the manual trades exception, FINRA explains that “as is the case today, under the Proposal members would be required to report the subject transactions to TRACE—including manual trades—‘as soon as practicable’ but no later than the applicable outer limit from the time of execution. Therefore, the current reporting requirements already account for the various ways that trades can be executed.”⁹⁹

The Commission finds that the Proposal would not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act because it creates exceptions for manual trades and firms with *de minimis* reporting activity. In doing so, the Proposal takes into account competitive and liquidity concerns that could arise as a result of the costs associated with complying with a shortened reporting timeframe that could lead some FINRA members to curtail their activities, or lead some FINRA members with less trade volume to exit the market, and thereby reasonably balances the benefits to market participants of increased transparency while mitigating the burdens of a shortened trade reporting deadline. In this regard, the Proposal is also reasonably designed to not permit unfair discrimination between brokers or dealers.

The Commission views the manual trades exception as facilitating greater transparency while still allowing needed time to report for trades with manual processes. Further, the phase-in of the manual trades exception’s five-minute outer limit over three years is reasonably designed to provide FINRA members time during which to assess trade execution and post-trade processes and make changes necessary to meet a shorter reporting deadline, thereby facilitating any changes to manual interventions currently employed by FINRA members to complete the trade execution or reporting process.

With respect to the *de minimis* exception, as discussed below, the exception reasonably and appropriately balances the burdens that would otherwise fall on FINRA members that process limited trade volume without diluting the overall benefits of the Proposal.¹⁰⁰

FINRA responded to the comments regarding the *de minimis* and manual trades exceptions, including regarding whether the exceptions are too narrow or too broad, as well as the potential impact of the costs associated with faster reporting for small broker-dealers.¹⁰¹ After carefully reviewing the Notice, Partial Amendment No. 1, and comment letters received, including the FINRA Letter, the Commission views the Proposal as striking a reasonable balance between requiring more contemporaneous transaction reporting and transparency and the burden of requiring all transactions to be reported within one minute.¹⁰² The Proposal both facilitates greater transparency through faster post-trade reporting and provides FINRA member firms with an exception from the one-minute reporting deadline that will permit continued reliance on manual processes and another for FINRA members that process limited trade volume. Additionally, the Commission disagrees with the comment that the exceptions “unnecessarily” deprive market participants of information; the Proposal and its exceptions are a reasonable balance between providing information to market participants, thereby increasing transparency, and mitigating the burdens of one-minute trade reporting.

C. De Minimis Exception

Several commenters specifically address the *de minimis* exception. Some commenters state support for the *de minimis* exception.¹⁰³ One of these commenters states the *de minimis* exception is appropriately tailored to protect minority, veteran, and women owned business enterprises and small dealers from incurring significant costs.¹⁰⁴ The commenter also states the proposed two-year look back period will prevent surprise application of the rule and allow newly impacted broker-

small FINRA members). Also, the Proposal would not phase out the *de minimis* exception, as requested by a commenter and opposed by another commenter. See *supra* notes 93 and 98 and accompanying text; see also new Supplementary Material .08 and *supra* section II.B.1.

¹⁰¹ See *infra* section III.C and III.D (discussing comments, and FINRA’s response, on the *de minimis* and manual trades exceptions, including those regarding the scope of the exceptions and impact on smaller broker-dealers).

¹⁰² See FINRA Letter at 2–7, 14–15.

¹⁰³ See, e.g., SIFMA Letter I at 9; Letter from Kenneth E. Bentsen, Jr., President and CEO, Securities Industry and Financial Markets Association (August 21, 2024) (“SIFMA Letter III”) at 2; BDA Letter I at 2.

¹⁰⁴ See SIFMA Letter I at 9; SIFMA Letter II at 7; see also BDA Letter II at 4 (“Smaller dealers need [the *de minimis*] exception because many conduct the trade reporting process entirely manually.”)

dealers time to comply.¹⁰⁵ Another commenter that supports the *de minimis* exception states that market participants falling under the threshold represent an insignificant portion of the market and that the exception will not materially affect market transparency.¹⁰⁶ Some commenters state opposition to the *de minimis* exception.¹⁰⁷ One of these commenters supports the logic behind the *de minimis* exception but states the proposed 4,000-trade report threshold is too low and insufficiently justified.¹⁰⁸ This commenter also requests FINRA expand the threshold or at minimum provide more analysis to support its proposed limit.¹⁰⁹ Another commenter that opposes the *de minimis* exception states FINRA did not sufficiently justify the need for the exception, nor its decisions to set the exception’s threshold at 4,000 annual trades and the lookback period for applicability of the threshold at two years.¹¹⁰ Additionally, this commenter states that the exception would create information asymmetries and could lead to gamesmanship, evasion, and market distortions.¹¹¹ Further, the commenter stated that this exception could allow a firm that “engaged in 5 trades in one year, and 100,000 trades” the next to continue its 15 minute reporting the following year.¹¹² In addition, the *de minimis* exception, the commenter stated, “could incentivize a firm seeking to mask its trading activities . . . to use an ‘excepted’ broker to effectuate its trading.”¹¹³

FINRA states “that the proposed *de minimis* exception balances the regulatory goal of providing for timelier reporting with the impact and burdens on members that are less active in this space, including smaller market participants. In response to *Regulatory Notice* 22–17, numerous commenters expressed concern regarding the impact that a one-minute reporting standard would have on small [FINRA] member firms, including minority, women, and veteran-owned broker-dealers. Some of these commenters believed that small broker-dealers would exit the market for fixed income secondary market trading

¹⁰⁵ See SIFMA Letter I at 9; SIFMA Letter II at 7.

¹⁰⁶ See BDA Letter II at 4.

¹⁰⁷ See, e.g., Falcon Letter I at 2–4; see also HMA Letter I at 9–11, 13 (this commenter also more broadly opposes the Proposal, see HMA Letter II).

¹⁰⁸ See Falcon Letter I at 2–3; Falcon Letter II at 2–3.

¹⁰⁹ See *id.*

¹¹⁰ See HMA Letter I at 11. As discussed above, this commenter supplemented its prior comments to more broadly object to the Proposal. See HMA Letter II at 1; *supra* note 69 and accompanying text.

¹¹¹ See HMA Letter I at 1 at 10.

¹¹² See *id.* at 11.

¹¹³ See *id.* at 10.

⁹⁹ FINRA Letter at 6 (citations omitted).

¹⁰⁰ See *infra* section III.C (discussing comments, and FINRA’s responses, on the *de minimis* exception, including FINRA’s data in support of the threshold and look-back period for the exception, as well as the Commission view that the exception strikes an appropriate balance between fulfilling the goal of increased transparency and mitigating any disproportionate cost of compliance on certain,

because of the high implementation and compliance costs and cautioned that this would harm retail investors that depend on small [FINRA] member firms for access to the market.”¹¹⁴

Accordingly, FINRA believes the Proposal adequately established the need for the *de minimis* exception.¹¹⁵

Additionally, FINRA states that “[w]ith respect to the 4,000-trade threshold (with a two-year lookback) for the *de minimis* exception, as discussed in the Proposal, FINRA believes that the proposed threshold is appropriately tailored to balance the compliance and implementation burdens on [FINRA] members with the benefits to transparency. Based on 2022 data, the proposed *de minimis* threshold would provide relief to 640 (out of 838 currently active) [FINRA] members that, in the aggregate, accounted for 1.41% of trades or 0.43% of the total par value traded. FINRA continues to believe that this threshold appropriately balances the benefits of timelier reporting with the potential costs of disrupting markets and disproportionately impacting less active and smaller participants. Additionally, based on FINRA’s analysis of historical trading data over the last five years, FINRA does not believe that some of the concerns raised by HMA about the two-year lookback are likely to occur (e.g., that a firm may go from five trades in one year to 100,000 the next). FINRA’s analysis of trading data indicates that, in reality, the difference between a one- and two-year lookback impacted only 11 firms annually, on average, whose activity increased over the 4,000-trade threshold by 67% on average and a maximum of 421%.”¹¹⁶

Further, FINRA responds to the comment that the exception may lead to “gamesmanship, evasion, and market distortions” by stating that “members relying on the *de minimis* exception continue to be subject to the requirement that they report their trades to TRACE as soon as practicable. Existing requirements under Rule 6730.03(a) make clear, among other things, that firms’ policies and procedures must be reasonably designed to comply with the ‘as soon as practicable’ reporting requirement by implementing systems that commence the trade reporting process at the time of execution without delay, and that ‘[i]n no event may a [FINRA] member purposely withhold trade reports, e.g., by programming its systems to delay reporting until the end of the reporting time period.’ Second, to the extent

commenters are concerned that market participants may begin routing orders to members qualifying for the *de minimis* exception to take advantage of the longer outer-limit reporting timeframe, FINRA notes that this would increase the member’s activity level and, if significant, would cause the firm to no longer be eligible for the *de minimis* exception. As with the manual trades exception, FINRA has extensive trading data history for members and can monitor for unusual trading patterns that might indicate gamesmanship or efforts to delay the reporting of large trades.”¹¹⁷

With respect to the *de minimis* exception, FINRA responded to the comments regarding whether the proposed 4,000-trade threshold is too low, including by providing data and analysis for the threshold and lookback period, and addressed the role of the exception in balancing the goal of timelier reporting and the burden on less active members, including smaller broker-dealers.¹¹⁸ After carefully reviewing the Notice, Partial Amendment No. 1, and comment letters received, including the FINRA Letter, the Commission views the *de minimis* exception as reasonably and appropriately balancing the burdens that would otherwise fall on FINRA members that process limited trade volume without diluting the overall benefits of the Proposal. As FINRA states, the *de minimis* exception is expected to cover 640 FINRA members, which account in aggregate for 1.41% of trades and 0.43% of total par value traded.¹¹⁹ The Commission is sensitive to comments cautioning that small broker-dealers may exit the market for fixed income secondary market trading because of the burdens associated with one-minute reporting.¹²⁰ Retaining the 15 minute outside limit on reporting transactions by FINRA members qualifying for the *de minimis* exception would avoid imposing the burdens of compliance with one-minute reporting on less active market participants, including smaller broker-dealers. At the same time, FINRA members qualifying for the *de minimis* exception report a relatively small portion of transactions. Accordingly, the Proposal strikes an appropriate balance between fulfilling the goal of increased transparency and mitigating any disproportionate cost of complying with a shorter reporting

deadline on certain, small FINRA members.

D. Manual Trades Exception

Several commenters offer specific views about the scope of the manual trades exception. Some commenters characterize the manual trades exception as essential to ensuring compliance with the rule.¹²¹ One commenter states that the exception should be expanded to include certain fully electronic transactions that cannot feasibly be reported within one minute, such as transactions with a large number of post-trade allocations, batch-processed trades, and trades involving multiple systems in trade workflow.¹²² This commenter states that transactions with a large number of post-trade allocations are especially difficult to report within one minute for broker-dealers also registered as investment advisers.¹²³ Other commenters state support for FINRA’s proposal to apply the exception to a scenario where a firm has not previously traded a bond.¹²⁴ A commenter also states that FINRA should harmonize the scope of the manual trades exception with a similar proposal by the Municipal Securities Rulemaking Board (“MSRB”) that would apply to transactions in municipal securities.¹²⁵ In addition, this commenter describes certain scenarios that could be experienced by a reporting firm, questioning whether the manual trades exception would apply and suggesting a dialogue with industry about such scenarios.¹²⁶ A different commenter suggests that the exception apply to “any manual intervention in

¹²¹ See BDA Letter I at 1; BDA Letter II at 2; FIF Letter I at 2; FIF Letter III at 2; SIFMA Letter I at 6; SIFMA Letter II at 3–6; SIFMA Letter III at 2; FHN Letter at 2.

¹²² See SIFMA Letter I at 7–9; SIFMA Letter II at 6–7; SIFMA Letter III at 2; see also LPL Letter at 2.

¹²³ See SIFMA Letter I at 7–8; SIFMA Letter II at 5–7; SIFMA Letter III at 4; see also BDA Letter I at 3–4; BDA Letter II at 2 (stating that reporting post-trade allocations in one minute sometimes “is not feasible even in a fully automated environment”); FIF Letter I at 3; Falcon Letter II at 4 (stating that the concern about manual allocations also extends to broker-dealers that are not dual-registrants).

¹²⁴ See FIF Letter I at 4; see also FIF Letter III at 3 (requesting FINRA provide guidance that a firm would not be held to the applicable reporting timeframe in a scenario where FINRA is delayed in providing a symbol requested by a firm); BDA Letter III at 2 (stating that it would be “difficult or impossible to report in less than 15 minutes” trades when a firm trades a bond for the first time); SIFMA Letter III at n. 6 (referencing the time it currently takes to set up and report new bonds using FINRA’s TRAQS and New Issue Portal).

¹²⁵ See FIF Letter I at 3.

¹²⁶ See Letter from Howard Meyerson, Managing Director, Financial Information Forum (February 26, 2024) (“FIF Letter II”) at 2–4; FIF Letter I at 3–4; FIF Letter III at 3.

¹¹⁷ *Id.* at 15.

¹¹⁸ See *supra* notes 114–116 and accompanying text.

¹¹⁹ See Notice, 89 FR at 5043.

¹²⁰ See *supra* note 90.

¹¹⁴ FINRA Letter at 14 (citations omitted).

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 14–15 (citations omitted).

the trade execution or reporting process.”¹²⁷ Another commenter states that there should not be a manual trades exception, nor a distinction between manual and electronic trades at all.¹²⁸

Several commenters state the manual trades exception is too broad.¹²⁹ Some of these commenters state that FINRA failed to meet its burden to demonstrate consistency with the Act, particularly by failing to estimate the number of transactions expected to qualify for the manual trades exception,¹³⁰ and one of these commenters states that the manual trades exception was not included in FINRA Regulatory Notice 22–17, which was issued by FINRA to solicit comment on shortening the trade reporting timeline from 15 minutes to one minute for certain TRACE-Eligible securities.¹³¹ These commenters questioning the lack of estimates in the Proposal raise the issue that a large proportion of the total number of trades currently reported outside of one minute could fall within the proposed rule’s manual trades exception, undermining the goal of increasing post-trade transparency.¹³² These commenters also raise the issue that firms could build manual steps into the trade execution process as a means of qualifying for the longer manual trades reporting window.¹³³ One commenter responds to this issue by stating that under the Proposal any action purposefully intended to extend the trade reporting time is a violation.¹³⁴ The commenter also states that there is no evidence to suggest market participants intentionally delay reporting transactions, nor do market participants have any incentive to do so.¹³⁵ This commenter disagrees with the comment that FINRA has not met

the requirements of the Act, stating it is convinced FINRA demonstrated the Proposal’s consistency with the Act by providing supporting information and statistics throughout the rulemaking process.¹³⁶

FINRA states that it disagrees with the comments that the manual trades exception should be eliminated and that the distinction between manual and electronic trades should not exist or that the manual trades exception should be expanded to include certain fully electronic trades. Specifically, as discussed above, FINRA states, “as is the case today, under the Proposal members would be required to report the subject transactions to TRACE—including manual trades—‘as soon as practicable’ but no later than the applicable outer limit from the time of execution. Therefore, the current reporting requirements already account for the various ways that trades can be executed and the resultant differences in the reporting times—some trades may be reported in 30 seconds and others in two minutes today, depending upon the mode of execution and reporting, and what is practicable under the circumstances. Thus, the Proposal is not introducing tiers or causing additional variance; rather it is reducing the permissible variance by significantly refining the outer limit for both manual and electronic trades. The proposed five-minute outer limit for reporting that eventually would be applicable to manual trades recognizes, consistent with other FINRA trade reporting rules, that trades that are manually executed or reported may not be able to be reported as quickly as trades that are electronically executed and reported.”¹³⁷

With respect to large post-trade allocations, batch-processed trades, and trades involving multiple systems in trade workflow, FINRA states that it “contemplates that the manual trades exception would apply ‘where a member agrees to trade a basket of securities at a single price and manual action is required to calculate the price of component securities in the basket or to book and report the trade in component securities to TRACE.’ However, if manual action was not required to calculate the price of component securities included in the basket or other steps necessary to book and report the trades to TRACE, then the manual trades exception would not be available. Therefore, for example, if the firm employed an automated process to calculate prices for, and book

and report the trades in, the component securities, the manual trades exception would not be available since this process was completed electronically without manual intervention.”¹³⁸ FINRA also states that, as discussed in the Proposal, “FINRA examined transaction reporting times for trades that were subsequently suballocated across multiple accounts and found that, for allocated trades, 68% were reported within one minute, and 90.6% were reported within three minutes.”¹³⁹ FINRA also stated that it “was unable to distinguish between allocations that involved manual intervention from fully electronic allocations in the data; therefore, reporting within one minute for fully electronic allocations may be greater than 68%.”¹⁴⁰ As discussed above, FINRA also acknowledges concerns with respect to feasibility of one-minute reporting, especially with respect to fully electronic allocated trades, and describes its approach to enforcement of late reporting of transactions to TRACE.¹⁴¹

With respect to post-trade allocations by broker-dealers also registered as investment advisers, FINRA states that the proposed rule “contemplates that the manual trades exception would apply ‘where allocations to individual accounts must be manually input in connection with a trade by a dually-registered broker-dealer/investment adviser.’”¹⁴²

With respect to a scenario where a firm has not previously traded a bond, FINRA states that the proposed rule “contemplates that the manual trades exception would be available ‘where a member trades a bond for the first time and additional manual steps are necessary to set the bond up in the firm’s systems to book and report the trade (e.g., entering the CUSIP number and associated bond data into the firm’s system).’”¹⁴³

With respect to the comment that the manual trades exception incentivizes firms to build in manual processes in order to qualify for the exception, FINRA states that it “has explicitly considered and addressed this concern in the Proposal. Specifically, the text of the manual trades exception would explicitly prohibit a [FINRA] member from ‘purposefully delay[ing] the execution or reporting of a transaction by handling a trade manually or

¹²⁷ See Falcon Letter II at 4.

¹²⁸ See Citadel Letter II at 1–2.

¹²⁹ See, e.g., HMA Letter II at 2–3; HMA Letter I at 11–12; Citadel Letter I at 2–3; FIA PTG Letter at 2–4.

¹³⁰ See Citadel Letter I at 1–3; Citadel Letter II at 3–5; FIA PTG Letter at 2–3; see also Falcon Letter I at 1; Falcon Letter II at 2 (both stating that FINRA did not adequately justify the exceptions to the rule).

¹³¹ See Citadel Letter I at 2.

¹³² See Citadel Letter I at 2–3; FIA PTG Letter at 2; Citadel Letter II at 1–3.

¹³³ See Citadel Letter I at 3; FIA PTG at 3; see also HMA Letter I at 12 (stating that the Proposal as originally proposed did “not assuage our concerns that firms may intentionally add a ‘manual’ component to their post-execution processes so as to avoid timely reporting (and dissemination) of their trading activity.”); HMA Letter II at 3 (stating that the Proposal, as modified by Partial Amendment No. 1, did not materially revise the extremely broad examples of manual trades and further offer relevant guidance as to when a manual component or process may nevertheless not qualify for the exception, and would lead to market abuses); *supra* note 92 and accompanying text.

¹³⁴ BDA Letter I at 3.

¹³⁵ *Id.*

¹³⁶ See BDA Letter II at 4.

¹³⁷ FINRA Letter at 6 (citations omitted).

¹³⁸ *Id.* at 8 (citations omitted, citing Notice, 89 FR at 5036, 5045).

¹³⁹ *Id.* at 17 (citing Notice, 89 FR at 5034, 5041).

¹⁴⁰ *Id.* at 17 (citing Notice, 89 FR at 5034, 5041 n.32).

¹⁴¹ See *supra* note 75 and accompanying text.

¹⁴² *Id.* at 7–8 (citing Notice, 89 FR at 5036, 5045).

¹⁴³ *Id.* at 7 (citing Notice, 89 FR at 5036, 5045).

introducing manual steps following the Time of Execution.’ FINRA also is very familiar with [FINRA] members’ usual reporting timeframes and possesses extensive data with which to establish a baseline for comparison in identifying changes in behavior. As noted in the Proposal, FINRA will review [FINRA] members’ use of the manual trades exception and their reporting timeliness in light of their historic behaviors reporting transactions to TRACE. Thus, FINRA believes that the manual trades exception continues to be appropriate and balanced in order to support the overall goal of the Proposal—facilitating more timely access to market information—while ensuring that compliance is achievable for the subset of trades that rely on manual intervention between the trade’s time of execution and when it is reported to TRACE.”¹⁴⁴

The Proposal both facilitates greater transparency through faster post-trade reporting and provides FINRA member firms with an exception from the one-minute reporting deadline that will permit continued reliance on manual processes. The Commission agrees with FINRA’s statement that “the proposed five-minute outer limit for reporting that eventually would be applicable to manual trades recognizes, consistent with other FINRA trade reporting rules, that trades that are manually executed or reported may not be able to be reported as quickly as trades that are electronically executed and reported.”¹⁴⁵ Moreover, as described above,¹⁴⁶ FINRA provided additional discussion in its letter in response to specific scenarios raised by commenters regarding the application of the proposed manual trades exception to large post-trade allocations, batch-processed trades, trades involving multiple systems in trade workflow, post-trade allocations by broker-dealers also registered as investment advisers, and scenarios where firms have not previously traded a bond by clarifying that such scenarios would not qualify for the manual trades exception when manual intervention between the time of execution and the trade report does not occur. FINRA also provided data in support of not including fully electronic allocated trades in the manual trades exception and described its regulatory standard for potential violations of its reporting rules. Finally, with respect to the comment that the scope of the manual trades exception should be

harmonized with the MSRB’s proposal that would apply to transactions in municipal securities, the definitions of “manual trades” in proposed Supplementary Material .09 to FINRA Rule 6730 and a “trade with a manual component” in proposed MSRB Rule G-14(d)(xii)¹⁴⁷ are consistent.

Additionally, the Proposal’s manual trades exception is appropriately tailored for facilitating more timely access to market information as well as promoting compliance, and, as FINRA discussed in the Proposal, the manual trades exception included in the Proposal was informed by comments received in response to FINRA Regulatory Notice 22–17. FINRA is not required under the Act to publish a FINRA notice soliciting comment on a potential proposed rule change prior to filing such change as a proposed rule change with the Commission. FINRA included the manual trades exception in the Proposal as well as a discussion of comments received on FINRA Regulatory Notice 22–17¹⁴⁸ and the Commission provided three 21-day public comment periods in connection with publication of the Notice, the OIP, and Partial Amendment No. 1. Furthermore, FINRA provided additional analysis and data in its comment letter.¹⁴⁹ As FINRA states, “the manual trades exception appropriately accommodates transactions that cannot feasibly be reported within one minute, balancing the burdens on members with the benefits to transparency.”¹⁵⁰ The Commission agrees: the manual trades exception provides a reasonable accommodation for transactions that cannot feasibly be reported within one minute, and FINRA has provided sufficient justification for the Proposal. The Commission anticipates that FINRA will monitor its members to ensure compliance with the “as soon as practicable” requirement and detect changes in reporting behavior. This should address concerns about manipulation. In particular, this should address comments regarding FINRA members purposefully delaying the reporting of transactions by building manual steps into the trade execution process and help ensure that the manual trades exception would not result in a degradation in trade reporting timeliness. Additionally, in response to comments concerning FINRA’s lack of

estimates of the number of trades that are expected to qualify for the manual trades exception, proposed changes to FINRA Rule 6730(d)(4) would require FINRA members to “append a manual trade indicator to the trade report so that FINRA can identify manual trades. The new manual trade indicator would be required regardless of whether the [FINRA] member reported the manual trade outside of the one-minute timeframe in reliance on the manual trades exception, which would provide FINRA with important insights into manual trading and the use of the exception.”¹⁵¹ Accordingly, the addition of the manual trade indicator will allow FINRA to collect data on the extent to which manual processes are employed by FINRA members, data that, due to the current lack of a manual trade indicator, is not currently available.

1. Manual Trade Indicator

Several commenters offer specific views about the manual trade indicator. Some commenters state it would be more operationally feasible to flag trades subject to one-minute reporting, rather than flagging all manual trades.¹⁵² One of these commenters states that requiring personnel to identify the manual component of a trade will hinder compliance and delay reporting.¹⁵³ Some commenters state that FINRA should offer an interim period during which firms are permitted, but not required, to report the manual trade indicator.¹⁵⁴ One commenter requests clarification regarding the operation of the manual trade indicator in specific scenarios.¹⁵⁵

With respect to the manual trade indicator, FINRA states that rather than identifying electronic trades, “identifying manual trades would be more appropriate from a regulatory perspective because manual trades are the universe of trades for which additional time may be warranted under the proposed framework, and requiring members to identify these trades would align the responsibility for assessing and representing the nature of the trade to FINRA with the legal framework for reporting. As stated in the Proposal, FINRA believes that the proposed manual trade indicator would provide FINRA with important insights into manual trading and the use of the exception.”¹⁵⁶

¹⁵¹ See Notice, 89 FR at 5036–5037.

¹⁵² See BDA Letter I at 3; SIFMA Letter I at 9; SIFMA Letter II at 7–8.

¹⁵³ See SIFMA Letter II at 7.

¹⁵⁴ See FIF Letter I at 6; SIFMA Letter II at 8.

¹⁵⁵ See, e.g., FIF Letter I at 4–5.

¹⁵⁶ FINRA Letter at 12.

¹⁴⁴ FINRA Letter at 6–7 (citations omitted).

¹⁴⁵ See *supra* note 137 and accompanying text.

¹⁴⁶ See *supra* notes 137–143 and accompanying text.

¹⁴⁷ See Exchange Act Release No. 99402 (Jan. 19, 2024), 89 FR 5384.

¹⁴⁸ See Notice, 89 FR at 5044–5046.

¹⁴⁹ See, e.g., notes 184–185 and accompanying text.

¹⁵⁰ See FINRA Letter at 10.

FINRA also responds to one commenter's requests for clarification about certain scenarios. With respect to the commenter's request for clarification about whether the manual trade indicator must be reported for trades that are manually corrected, FINRA states that "As stated in the Proposal, '[t]o the extent the trade was originally fully electronic, when the member amends the trade report, it should add the Manual Trade Indicator.'"¹⁵⁷ For a commenter's request for clarification about whether the manual trade indicator is applicable to general systems fixes necessary to correct a technical issue that adversely impacted trade reporting, FINRA states that "the manual trade indicator must be appended '[i]f reporting a transaction that is manually executed or where such member must manually enter any of the trade details or information necessary for reporting the trade through the TRAQS website or into a system that facilitates trade reporting to TRACE.'"¹⁵⁸ Finally, in response to a commenter's request for clarification that the manual trade indicator would not be included in TRACE's trade report matching criteria, "FINRA confirms that it does not intend to use the manual trade indicator in TRACE's trade report matching criteria."¹⁵⁹

The Commission agrees with FINRA that the indicator should identify manual trades instead of electronic trades, and that the manual trade indicator will provide FINRA with important insight into the extent to which FINRA members utilize manual intervention between execution and trade reporting. Electronic trades will be required to be reported as soon as practicable but no later than one minute and adding a requirement for FINRA members to identify electronic trades could introduce a delay in reporting such electronic trades. Further, to the extent that the manual trade indicator requirement adds a burden on reporting manual trades that otherwise would not be present on electronic trades, FINRA members may have an incentive to eliminate manual intervention to complete the trade execution or reporting process, which would result in a greater number of electronic trades facilitating greater transparency through faster post-trade reporting. Accordingly, the manual trade indicator requirement reasonably balances the benefits gained against any compliance hinderance or reporting delay for manual trades. The Commission is not persuaded by the

view that there should be an interim period for voluntary use of the manual trade indicator because such a period would reduce the benefits of the insights into manual trading and the use of the exception.

2. Five-Minute Reporting Phase-In

Several commenters address the gradual phase-in of five-minute reporting written into the proposed rule for manual trades.¹⁶⁰ Multiple commenters request FINRA propose for notice and comment each time it seeks to reduce the timeframe.¹⁶¹ One of these commenters also states that FINRA must consider that the proposed rule will be implemented alongside other regulatory initiatives, such as the shortened securities settlement cycle (T+1), and potentially other rules that have been proposed.¹⁶² Other commenters state that the absence of data in the Proposal justifying accelerated reporting timeframes for manual trades reflects insufficient understanding of the complexities involved in manual trade reporting.¹⁶³ Another commenter states that FINRA's amendment to extend the 10-minute reporting timeframe from one year to two is "encouraging."¹⁶⁴

FINRA states that it "appreciates that members may be concerned by the degree to which some manual trades are not reported within five minutes today. In response to these comments, FINRA has amended the manual trades exception to provide FINRA members

with an additional year to transition to five-minute reporting for manual trades."¹⁶⁵ In particular, a FINRA member relying on the manual trades exception will be required to report the manual trade "as soon as practicable and no later than within 15 minutes of the time of execution (for up to one calendar year from the effectiveness of the proposed amendments), within 10 minutes of the time of execution (for up to three calendar years from the effectiveness of the proposed amendments), and within five minutes of the time of execution (three or more calendar years from the effectiveness of the proposed amendments)."¹⁶⁶ FINRA's original proposal, as described in the Notice, would have required FINRA members relying on the manual trades exception to report such manual trades as soon as practicable but no later than five minutes of the time of execution two or more calendar years from the effectiveness of the proposed amendments.

In addition to this extended phase-in timeline, FINRA states that it "intends to closely study the trade reporting data (this will be facilitated by the manual trade indicator, which will allow FINRA to identify manual trades) and will continue its engagement with [FINRA] members on whether feasibility concerns continue to exist once firms review and revise their trade reporting processes in light of the Proposal. Moreover, within nine to 12 months of the effectiveness of the 10-minute outer-limit reporting timeframe for manual trades, FINRA intends to publish a Regulatory Notice soliciting comment from [FINRA] members regarding the operation and impact of the reduced reporting timeframe for these manual trades. FINRA would evaluate TRACE data and the comments received and consider if any measures are appropriate."¹⁶⁷ FINRA states that such measures could include filing a "proposed rule change with the Commission prior to the effectiveness of the five-minute reporting timeframe to extend the implementation of, or eliminate, the five-minute reporting requirement for manual trades, as warranted."¹⁶⁸

The Commission views the phase-in of the manual trades exception's five-minute outer limit over three years as reasonably designed to provide FINRA members time during which to assess trade execution and post-trade processes

¹⁶⁰ See, e.g., ICI Letter at 3–4; Falcon Letter at 4; SIFMA Letter I at 6; SIFMA Letter II at 6; BDA Letter I at 2–3; ASA Letter II at 2.

¹⁶¹ See ICI Letter at 3; see also SIFMA Letter I at 6 (stating that FINRA should conduct an impact assessment before reducing the reporting window for manual trades to five minutes); SIFMA Letter II at 6; ASA Letter II at 2 (stating that the proposal to gradually phase in the reporting window for manual trades without opportunity for formal industry input presents risk and complicates compliance for market participants); Falcon Letter at 4 (stating that FINRA must produce supporting data before proposing a mandatory phase-in period for the manual trades exception); LPL Letter at 2 (stating FINRA should examine impact on liquidity, depth, concentration, and transparency prior to further decreasing reporting times); BDA Letter II at 3, 5 (asking FINRA to commit to seeking public comment before any reduction in trade reporting times for manual trades takes effect). But see BDA Letter I at 3 (stating support for the phase-in approach, but asking FINRA to communicate with industry during the transition period regarding operational roadblocks that could arise). One commenter states that extension of the phase-in in Partial Amendment No. 1 does not address its earlier comment that any alteration of the compliance threshold should necessitate additional input from stakeholders, such as through a formal request for comment or a new proposal. See ASA Letter III at 1.

¹⁶² See ICI Letter at 3–4.

¹⁶³ See ASA Letter II at 2; see also Falcon Letter II at 3–4.

¹⁶⁴ SIFMA Letter III at 3.

¹⁶⁵ FINRA Letter at 10–11 (citations omitted).

¹⁶⁶ *Id.* at 11; see also Partial Amendment No. 1, 89 FR at 61515.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁵⁷ *Id.* at 12.

¹⁵⁸ *Id.* at 13.

¹⁵⁹ *Id.*

and make changes necessary to meet a shorter reporting deadline. As part of the Proposal, FINRA included in new Supplementary Material .09 to FINRA Rule 6730 a schedule for implementing reductions in the deadline for reporting trades eligible for the manual trades exception. The three-year phase-in of the manual trades exception reasonably balances the costs of implementation with the goal of increased transparency, by giving FINRA members more time to meet the requirements. FINRA need not provide an additional round of notice and comment for every phase of the transition. But FINRA nonetheless intends to engage with and solicit comment from FINRA members throughout the phase-in period regarding implementation of the reduced reporting requirement for manual trades.¹⁶⁹ The Commission will consider any future proposed rule changes filed with the Commission regarding the implementation. Additionally, in response to the comment stating that the Proposal would need to be implemented alongside other regulatory initiatives, the Commission views FINRA's statement that it "will endeavor to publish updated technical specifications as far as possible in advance of the effective date"¹⁷⁰ as a reasonable response, as the more time FINRA members are afforded to implement system changes to conform to updated technical specifications in support of the Proposal, the greater flexibility FINRA members will have to schedule such system changes. Further, in response to the comment specifically referencing the implementation of amendments to SEC rules to shorten the standard settlement cycle to T+1, the compliance date for such amendments was May 28, 2024.¹⁷¹ In addition, the other proposals cited by the commenter have not been adopted, so FINRA cannot take such possible regulatory changes into consideration in determining the compliance dates as part of this Proposal.

E. Reporting Requirement Consistency

Several commenters discuss the consistent application of reporting requirements,¹⁷² including some that state that the differing reporting windows for manual and electronic trades violate the Act by discriminating based on the mode of execution and

unduly burdening competition.¹⁷³ Two commenters describe the potential negative consequences of applying different levels of post-trade transparency depending on a trade's mode of execution.¹⁷⁴ One of these commenters states that "[t]he massive disparity in timeliness of reporting between the two execution methods not only creates a significant risk of losing the benefits of transparency, but also creates new opportunities to manipulate markets."¹⁷⁵

Another commenter raises the issue of different reporting requirements under the proposal depending on a trade's time of execution.¹⁷⁶ The commenter states that under the current rule, trades executed when TRACE is closed must be reported within 15 minutes of TRACE being open, mirroring the deadline for reporting of trades executed when TRACE is open.¹⁷⁷ But, the commenter continues, under the Proposal, trades executed outside of the hours when TRACE is open will still be subject to the deadline to report within 15 minutes of TRACE being open while trades executed when TRACE is open will be subject to the new one minute requirement.¹⁷⁸ The commenter urges consistent reporting times in this scenario.¹⁷⁹ One commenter responds to this comment, stating that few bond trades take place after hours because of limited liquidity and that no evidence suggests market participants abuse existing exceptions to permit next-day reporting of after-hours trades.¹⁸⁰

In response to the comment to make consistent the different times of reporting trades executed when TRACE is closed and open, FINRA states that "the continued application of a 15-minute reporting timeframe to afterhours trades would impact a small portion of trading activity—only 1.18% of total par value. Consistent with [FINRA] members' obligation to report trades as soon as practicable, a significant portion of these trades are already reported well before the 15-minute outer limit, (e.g., over 90% of trades executed before 8:00 a.m. or after 6:29 p.m. ET or on a nonbusiness day were reported within three minutes of the TRACE system open), and FINRA's analysis of trading near the close of TRACE system hours found no

indication that market participants execute trades near the close of TRACE system hours to delay reporting. Accordingly, FINRA does not believe, at this time, that the potential benefits of a one-minute reporting requirement for afterhours trades outweigh the burdens such a requirement may impose. In particular, FINRA is sensitive to the concerns previously expressed by commenters that reporting afterhours trades within one minute of the TRACE system open would present operational obstacles. FINRA also notes that the Proposal's continued application of a 15-minute reporting timeframe for afterhours trades is consistent with the rules governing other trade reporting facilities."¹⁸¹

With respect to the potential negative consequences of applying different levels of post-trade transparency depending on a trade's mode of execution, FINRA states that "as is the case today, under the Proposal members would be required to report the subject transactions to TRACE—including manual trades—"as soon as practicable" but no later than the applicable outer limit from the time of execution. Therefore, the current reporting requirements already account for the various ways that trades can be executed and the resultant differences in the reporting times."¹⁸²

The Proposal will set three outside limits for reporting transactions: a one-minute default deadline, a 15-minute deadline that will shorten to five minutes three years after the Proposal becomes operative for transactions eligible for the manual trades exception, and a 15-minute deadline for FINRA member firms with de minimis reporting activity. The Commission disagrees with the comment that this will result in varying levels of post-trade transparency or create new opportunities for market manipulation.¹⁸³ The Proposal's varying reporting deadlines do not change the existing requirement that transactions be reported as soon as practicable, which applies to all transactions covered by the Proposal, and is accommodative of unique aspects of different transactions. Because of the current "as soon as practicable" requirement, FINRA-provided data show that 82.9% of transactions are reported within one minute, 97.6% reported within five minutes, and

¹⁷³ See Citadel Letter I at 3; FIA PTG Letter at 3–4.

¹⁷⁴ See Citadel Letter I at 1–3; HMA Letter II at 3.

¹⁷⁵ See HMA Letter II at 3.

¹⁷⁶ See HMA Letter I at 8.

¹⁷⁷ See *id.*

¹⁷⁸ See *id.*

¹⁷⁹ See HMA Letter I at 9.

¹⁸⁰ BDA Letter II at 3.

¹⁸¹ FINRA Letter at 16–17 (citations omitted).

¹⁸² FINRA Letter at 6 (citations omitted); see also *supra* section III.D (discussing comments and responses, including the Commission's views, on the potential for manipulation).

¹⁸³ See *supra* notes 174 and 176.

¹⁶⁹ See *supra* note 167 and accompanying text.

¹⁷⁰ FINRA Letter at 18.

¹⁷¹ See Securities Exchange Act Release No. 96930 (February 15, 2023), 88 FR 13872 (March 6, 2023); see also 17 CFR 240.15c6–1.

¹⁷² See, e.g., Citadel Letter I at 1–3; HMA Letter II at 1–3; HMA Letter I at 8–9; BDA Letter II at 3.

99.4% reported within 15 minutes.¹⁸⁴ Accordingly, transaction reporting times currently are variable. However, “FINRA estimates that, after adjusting for the proposed *de minimis* exception and prior to accounting for the manual exception, the Proposal could result in up to 16.4% of current annual trading volume, or up to 6.1 million trades and 20 trillion dollars in par value, being reported faster. As further detailed in the Proposal, for non-ATS trades (some of which may qualify for the manual trades exception), 96.9% were reported within five minutes. Given that some non-ATS trades are fully electronic while others involve manual intervention between execution and trade reporting, FINRA conservatively estimates that the Proposal would result in at least another 2.03%, or over 755,000 trades representing approximately \$3.702 trillion traded (accounting for the impact of the proposed *de minimis* exception), being reported faster.”¹⁸⁵ Additionally, FINRA states that “[a]s evidenced by FINRA’s analysis of trades executed between one and 15 minutes after a prior trade of the same bond but before the prior trade was reported, the Proposal could potentially benefit the ability to evaluate pricing in a substantial amount of trades—over 486,100 corporate bond trades alone representing approximately \$459.6 billion traded (accounting for the impact of the proposed *de minimis* exception).”¹⁸⁶ Thus, the Proposal will reduce variation in reporting times by shortening the outer limit reporting time for FINRA member firms with more than *de minimis* reportable activity.

A similar proposed rule change by the MSRB,¹⁸⁷ on which the MSRB closely coordinated with FINRA,¹⁸⁸ would result in a consistent standard for trade reporting for municipal securities and the TRACE-Eligible Securities covered by the Proposal. Accordingly, the Commission finds that the Proposal would foster cooperation and coordination between the MSRB and FINRA by establishing consistent trade reporting requirements across various classes of fixed income securities. Consistent trade reporting requirements for municipal securities covered by MSRB rules and the TRACE-Eligible Securities covered by the Proposal also

may reduce compliance burdens resulting from inconsistent obligations and standards for different classes of fixed income securities.

F. Implementation Period

Some commenters address the implementation period.¹⁸⁹ Two commenters request an implementation period of two years from the time of approval due to the high cost of compliance.¹⁹⁰ Another commenter states the cost of implementing the proposal is anticipated to be especially high for smaller firms and suggests an implementation period of at least 18 months from the date of publication of updated technical specifications and guidance.¹⁹¹ The commenter also requests that FINRA provide an expanded free testing period of 90 days instead of the standard free testing period of 30 days.¹⁹²

FINRA responds that it “intends to provide [FINRA] members with a sufficient implementation timeframe (for example, approximately within 18 months from any SEC approval) to make the changes necessary to comply with the Proposal. If approved by the SEC, FINRA will announce the effective date of the Proposal in a *Regulatory Notice*. As is generally the case for TRACE rule changes, FINRA will endeavor to publish updated technical specifications as far as possible in advance of the effective date(s) and will work with [FINRA] members to provide interpretive guidance, where needed.”¹⁹³

The Commission views FINRA’s statements with respect to implementation as reasonable and appropriate. As stated above, FINRA intends to provide FINRA members with a sufficient implementation timeframe, publish updated technical specifications as far as possible in advance of the effective date, and be responsive to requests for interpretive guidance. FINRA represents that it will announce the effective date of the proposed rule change in a FINRA Regulatory Notice.

G. Consistency With the Administrative Procedure Act (“APA”)

One commenter questions the proposed rule’s consistency with the APA.¹⁹⁴ This commenter asserts that FINRA filed the proposed rule at the direction of the Commission, and objects to the Commission’s alleged use of self-regulatory organizations such as FINRA “as a conduit to carry out rulemakings that are the ultimate responsibility of the Commission.”¹⁹⁵ The commenter further argues that there is “no demonstrable market failure in the fixed income markets that would justify reducing the reporting timeframe from 15 minutes to 1 minute.”¹⁹⁶

The Commission did not direct FINRA to file the proposed rule and it is not using FINRA as a conduit to enact the proposed rule.¹⁹⁷ Rather, as FINRA explains, FINRA reassessed the TRACE trade reporting timeframe because FINRA believes that it is “appropriate and prudent to consider whether this timeframe continues to meet regulatory objectives given the passage of time and the changes in the fixed income securities industry in the intervening years.”¹⁹⁸ FINRA designed the Proposal itself based on “extensive data analysis,” “carefully consider[ing] the different ways trades can be executed in the fixed income markets and craft[ing] the manual trades exception to address a range of execution and reporting scenarios to account for these differences.”¹⁹⁹ In support of the Proposal, FINRA states that it “represents an important step in modernizing the trade reporting timeframes for TRACE-eligible securities to facilitate more timely transaction data, enhancing transparency and the value of disseminated transaction data by allowing investors and other market participants to obtain and evaluate more timely pricing information for the impacted securities.”²⁰⁰

¹⁹⁴ See ASA Letter III at 2–3; ASA Letter II at 2; ASA Letter I at 3.

¹⁹⁵ See *id.*; ASA Letter III at 2 & n.4.

¹⁹⁶ See ASA Letter III at 1; see also ASA Letter II at 2; ASA Letter I at 3.

¹⁹⁷ The commenter cites a speech by the Chair in stating to the contrary, but that speech does not specifically address the TRACE trade reporting timeframe at all. See ASA Letter III at 2 n.4 (citing Gary Gensler, Chair, Securities and Exchange Commission, Prepared Remarks before SEC Speaks: U.S. Capital Markets and the Public Good (Apr. 2, 2024) (transcript available at <https://www.sec.gov/newsroom/speeches-statements/prepared-remarks-sec-speaks-us-capital-markets-public-good>). And, in any event, the speech reflects the views of the Chair alone, not the Commission.

¹⁹⁸ FINRA Letter at 3.

¹⁹⁹ *Id.*

²⁰⁰ *Id.* at 3–4.

¹⁸⁴ See Notice, 89 FR at Table 1.

¹⁸⁵ FINRA Letter at 4 (citations omitted).

¹⁸⁶ *Id.* at 4–5.

¹⁸⁷ See *supra* note 147.

¹⁸⁸ See, e.g., Letter from Ernesto A. Lanza, Chief Regulatory and Policy Officer, MSRB, dated July 18, 2024, available at <https://www.sec.gov/comments/sr-msrb-2024-01/srmsrb202401-491663-1411646.pdf>.

¹⁸⁹ See, e.g., SIFMA Letter I at 10; BDA Letter I at 4; FIF Letter I at 5–7; SIFMA Letter II at 8.

¹⁹⁰ See SIFMA Letter I at 10; BDA Letter I at 4.

¹⁹¹ See FIF Letter I at 5.

¹⁹² See *id.* at 6–7; see also SIFMA Letter II at 8 (encouraging FINRA to eliminate its charge for testing and instead to offer no-cost testing). Comments related to FINRA’s free testing period and current practice to charge for testing after such free testing period are outside of the scope of this proposal.

¹⁹³ FINRA Letter at 18.

Nor does the Exchange Act require that a self-regulatory organization establish the existence of a market failure to justify a proposed rule change. Under Section 19(b) of the Exchange Act, the Commission must approve a rule change proposed by FINRA if the Commission finds that the proposed change is consistent with the requirements of the Act and the rules and regulations thereunder, including the requirements of section 15A(b).²⁰¹ For the reasons discussed above, the Commission finds that the Proposal is consistent with those requirements because, among other things, it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Proposal also does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.²⁰²

H. Consultation With the Treasury Department

Pursuant to section 19(b)(6) of the Act,²⁰³ the Commission has considered the sufficiency and appropriateness of existing laws and rules applicable to government securities brokers, government securities dealers, and their associated persons in approving the proposed rule change. Pursuant to section 19(b)(5) of the Act,²⁰⁴ the Commission consulted with and considered the views of the Treasury Department in determining whether to approve the proposed rule change. The

Treasury Department did not object to the proposed rule change.

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,²⁰⁵ that the proposed rule change (SR-FINRA-2024-004), as modified by Partial Amendment No. 1, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-22027 Filed 9-25-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101128; File No. SR-ISE-2024-03]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment Nos. 4 and 5 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 4, and 5, To Permit the Listing and Trading of Options on the iShares Bitcoin Trust

September 20, 2024.

I. Introduction

On January 9, 2024, Nasdaq ISE, LLC (“ISE” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act” or “Exchange Act”) ¹ and Rule 19b-4 thereunder,² a proposed rule change to list and trade options on exchange-traded product (“ETP”) shares that represent interests in the iShares Bitcoin Trust (“IBIT”).³ On January 11, 2024, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.

²⁰⁵ 15 U.S.C. 78s(b)(2).

²⁰⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ On January 10, 2024, the Commission approved proposals by NYSE Arca, Inc., The Nasdaq Stock Market LLC, and Cboe BZX Exchange, Inc. to list and trade the shares of 11 bitcoin-based commodity-based trust shares and trust units, including the iShares Bitcoin Trust, the Grayscale Bitcoin Trust, and the Bitwise Bitcoin ETF. See Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024) (order approving File Nos. SR-NYSEARCA-2021-90; SR-NYSEARCA-2023-44; SR-NYSEARCA-2023-58; SR-NASDAQ-2023-016; SR-NASDAQ-2023-019; SR-CboeBZX-2023-028; SR-CboeBZX-2023-038; SR-CboeBZX-2023-040; SR-CboeBZX-2023-042; SR-CboeBZX-2023-044; SR-CboeBZX-2023-072) (“Bitcoin ETP Order”).

On January 25, 2024, the proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register**.⁴ On March 6, 2024, pursuant to Section 19(b)(2) of the Act,⁵ the Commission designated a longer period within which to approve the Proposal, disapprove the Proposal, or institute proceedings to determine whether to disapprove the Proposal.⁶ On April 24, 2024, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act⁷ to determine whether to approve or disapprove the Proposal.⁸ On July 19, 2024, the Commission designated a longer time for Commission action on the Proposal.⁹ The Commission received comments addressing the proposed rule change.¹⁰ On May 23, 2024, ISE submitted a letter providing additional information regarding IBIT and other bitcoin-based ETPs.¹¹ On August 21, 2024, ISE submitted a second letter that provides additional analysis supporting the proposed position limit of 25,000 contracts for IBIT options.¹² The Exchange filed Amendment Nos. 2 and 3 to the Proposal on August 29, 2024, and September 12, 2024, respectively. On September 12, 2024, the Exchange withdrew Amendment Nos. 2 and 3 and filed Amendment No. 4 to the Proposal.¹³ The Exchange filed Amendment No. 5 to the Proposal on September 19, 2024.¹⁴ The Commission is publishing this notice to solicit comments on Amendment Nos. 4 and 5 from interested persons, and is approving the proposed rule change, as

⁴ See Securities Exchange Act Release No. 99396 (Jan. 19, 2024), 89 FR 5047 (Jan. 25, 2024) (“Notice” or “Proposal”).

⁵ 15 U.S.C. 78s(b)(2).

⁶ See Securities Exchange Act Release No. 99681 (Mar. 6, 2024), 89 FR 17886 (Mar. 12, 2024).

⁷ 15 U.S.C. 78s(b)(2)(B).

⁸ See Securities Exchange Act Release No. 100024 (Apr. 24, 2024), 89 FR 34290 (Apr. 30, 2024) (“Order Instituting Proceedings”).

⁹ See Securities Exchange Act Release No. 100567 (Jul. 19, 2024), 89 FR 60482 (Jul. 25, 2024).

¹⁰ Comment letters on the Proposal are available at <https://www.sec.gov/comments/sr-ise-2024-03/srise202403.htm>.

¹¹ See letter from Greg Ferrari, Vice President, U.S. Options, ISE, dated May 23, 2024 (“ISE Letter I”).

¹² See letter from Angela Dunn, Nasdaq ISE, LLC, dated Aug. 21, 2024 (“ISE Letter II”).

¹³ Amendment No. 4 amends ISE Options 9, Section 13, Supplementary Material .01 and ISE Options 9, Section 15, Supplementary Material .01, respectively, to establish position and exercise limits of 25,000 contracts for the proposed IBIT options.

¹⁴ Amendment No. 5 amends the Proposal to describe in greater detail the surveillance procedures that will apply to the trading of options on IBIT. The full text of Amendment Nos. 4 and 5 is available at the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/ISE/rulefilings>.

²⁰¹ 15 U.S.C. 78o-3(b), 78s(b)(2)(C).

²⁰² The commenter’s references to the Supreme Court’s decisions in *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024) and *Ohio v. EPA*, 144 S. Ct. 2040 (2024), are similarly misplaced. *Loper Bright* is inapposite because the question here is whether FINRA’s proposed rule change is consistent with the requirements of Section 15A(b)—in which case the Exchange Act requires the Commission to approve it—not whether the Commission would have statutory authority to adopt its own market-wide rule. And *Ohio* is inapposite because we explain above why commenters’ concerns do not establish that the Proposal is inconsistent with the requirements of the Act.

²⁰³ 15 U.S.C. 78s(b)(6).

²⁰⁴ 15 U.S.C. 78s(b)(5) (providing that the Commission “shall consult with and consider the views of the Secretary of the Treasury prior to approving a proposed rule filed by a registered securities association that primarily concerns conduct related to transactions in government securities, except where the Commission determines that an emergency exists requiring expeditious or summary action and publishes its reasons therefor”).

modified by Amendment Nos. 1, 4, and 5, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment Nos. 1, 4, and 5

As described in detail in the Notice, the Exchange proposed to amend its rules to permit the listing and trading of options on IBIT.¹⁵ The Exchange stated that options on IBIT would provide investors with a hedging and risk management tool to manage exposure to the price of bitcoin and bitcoin-related products and positions.¹⁶

Options on IBIT will be physically settled with American-style exercise.¹⁷ The Exchange stated that options on IBIT will be subject to the Exchange's respective initial and continued listing standards.¹⁸ The Exchange's initial listing standards require, among other things, that the security underlying a listed option be "characterized by a substantial number of outstanding shares that are widely held and actively traded."¹⁹ The Exchange stated that options on IBIT will trade in the same manner as other exchange-traded fund ("ETF") options, and that options on IBIT will be subject to the Exchange rules that currently apply to the listing and trading of all ETF options on the Exchange, including, for example, Exchange rules governing listing criteria, expiration and exercise prices, minimum increments, margin requirements, customer accounts, and trading halt procedures.²⁰

As initially proposed, the position and exercise limits for options on IBIT would have been determined pursuant to the Exchange's existing rules.²¹ Under these rules, the position and exercise limits applicable to an options class depend upon the trading volume and outstanding shares of the underlying security. Thus, position and exercise limits of 250,000, 200,000, 75,000, 50,000 or 25,000 contracts on the same side of the market would have applied to options on IBIT depending on the six-month trading volume and number of shares outstanding for IBIT.²²

In Amendment No. 4, the Exchange proposes to set the position and exercise limits for options on IBIT at 25,000 contracts regardless of the trading volume and shares outstanding for IBIT.²³ According to the Exchange, "this position limit is the lowest position limit available in the options industry, is extremely conservative and more than appropriate given the IBIT's market capitalization, average daily volume, and high number of outstanding shares."²⁴

The Exchange represents that the surveillance procedures that it applies to other ETF options will apply to options on IBIT, and that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior that might arise from listing and trading options on ETFs.²⁵ In Amendment No. 5, the Exchange more fully describes the surveillance procedures that will apply to options on IBIT. The Exchange states that it has an adequate surveillance program in place for options, and that the Exchange intends to apply the same program procedures to options on IBIT that it applies to the Exchange's other options products.²⁶ The Exchange states that its market surveillance staff would have access to the surveillances conducted by The Nasdaq Stock Market LLC ("Nasdaq") with respect to IBIT and would review activity in IBIT when conducting surveillances for market abuse or manipulation in the options on the IBIT.²⁷ Additionally, the Exchange states that it is a member of the Intermarket Surveillance Group ("ISG") under the Intermarket Surveillance Group Agreement, and that ISG

month trading volume of at least 40,000,000 shares, or most recent six-month trading volume of at least 30,000,000 shares and at least 120,000,000 shares currently outstanding. For an option to be eligible for the 200,000-contract limit, the underlying security must have most recent six-month trading volume of at least 80,000,000 shares, or most recent six-month trading volume of at least 60,000,000 shares and at least 240,000,000 shares currently outstanding. For an option to be eligible for the 250,000-contract limit, the security underlying the option must have most recent six-month trading volume of at least 100,000,000 shares, or most recent six-month trading volume of at least 75,000,000 shares and at least 300,000,000 shares currently outstanding. The 25,000-contract limit applies to options on underlying securities that do not qualify for a higher contract limit. See ISE Options 9, Section 13. In addition, ISE Options 9, Section 13, Supplementary Material .01 establishes higher position limits for options on certain ETFs.

²³ See Amendment 4.

²⁴ See *id.*

²⁵ See Notice, 89 FR at 5050.

²⁶ The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (e.g., spoofing, marking the close, pinging, phishing). See Amendment No. 5.

²⁷ See *id.*

members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets.²⁸ The Exchange further states that it has a Regulatory Services Agreement with the Financial Industry Regulatory Authority ("FINRA") and that, pursuant to a multi-party 17d-2 joint plan, all of the options exchanges allocate regulatory responsibilities to FINRA to conduct certain options-related market surveillance that are common to rules of all options exchanges.²⁹

The Exchange states that underlying shares of spot bitcoin ETPs, including IBIT, are also subject to safeguards related to addressing market abuse and manipulation.³⁰ The Exchange notes that the Commission stated in its order approving proposals by several exchanges to list and trade shares of spot bitcoin-based exchange-traded products ("Bitcoin ETP Order")³¹ that:

Each Exchange has a comprehensive surveillance-sharing agreement with the CME via their common membership in the Intermarket Surveillance Group. This facilitates the sharing of information that is available to the CME through its surveillance of its markets, including its surveillance of the CME bitcoin futures market.³²

The Exchange states that, given the consistently high correlation between the CME bitcoin futures market and the spot bitcoin market, as confirmed by the Commission through robust correlation analysis, the Commission was able to conclude that such surveillance sharing agreements could reasonably be "expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the [Bitcoin ETPs]."³³

²⁸ See *id.*

²⁹ Section 19(g)(1) of the Act, among other things, requires every SRO registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d-2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO ("common members"). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members. See Amendment No. 5.

³⁰ See Amendment No. 5.

³¹ See *supra* note 3.

³² See Amendment No. 5 (citing the Bitcoin ETP Order, 89 FR at 3009).

³³ See Amendment No. 5 (citing the Bitcoin ETP Order, 89 FR at 3010-11).

¹⁵ See *supra* note 4.

¹⁶ See Notice, 89 FR at 5051.

¹⁷ See *id.* at 5050.

¹⁸ See Notice, 89 FR at 5049. See also ISE Options 4, Section 3(a).

¹⁹ See Notice, 89 FR at 5049.

²⁰ See *id.* at 5050.

²¹ See *id.*

²² For an option to be eligible for the 50,000-contract limit, the security underlying the option must have most recent six-month trading volume of at least 20,000,000 shares, or most recent six-month trading volume of at least 15,000,000 shares and at least 40,000,000 shares currently outstanding. For an option to be eligible for the 75,000-contract limit, the underlying security must have most recent six-

In light of surveillance measures related to both options and futures, as well as the underlying Trust,³⁴ the Exchange believes that existing surveillance procedures are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading the proposed IBIT options.³⁵

The Exchange represents that it believes that both it and the Options Price Reporting Authority, LLC have the necessary systems capacity to handle the additional traffic associated with the listing of new series that may result from the introduction of options on IBIT.³⁶

The Proposal also amends ISE Options 4, Section 3(h) to replace the reference to the “ETFs Gold Trust” with a reference to the Aberdeen Standard Physical Gold Trust, the current name of the trust. In addition, the Proposal replaces incorrect cross-references to “Options 4, Section 3(h)(A)(i)” in ISE Options 4, Section 4(g) with references to the correct citation, “Options 4, Section 3(h)(i).”

III. Discussion and Commission Findings

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange,³⁷ and, in particular, the requirements of Section 6 of the Act.³⁸ Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,³⁹ which requires that an exchange have rules designed to prevent fraudulent and manipulative acts and practices, to remove impediments to and perfect the mechanism of a free and open market, and to protect investors and the public interest.

The Order Instituting Proceedings sought comment on several issues raised by the Proposal, including whether shares in the underlying bitcoin ETPs are “widely held and actively traded,” as required by ISE’s rules; whether the proposed bitcoin ETP options should be subject to the same position limits as stock options, and whether the available

supply in the markets for bitcoin should be considered in establishing position limits for options on the bitcoin ETPs; and the potential impact on market quality and function that could result from listing bitcoin ETP options.⁴⁰ Several commenters supported the Proposal, generally stating that the proposed options would help investors to hedge their positions and manage crypto-related risk.⁴¹ Other commenters raised concerns regarding the potential risks of the proposed options to individual investors and the financial system.⁴²

A. Widely Held and Actively Traded

The Exchange’s initial listing standards require, among other things, that the security underlying a listed option be “characterized by a substantial number of outstanding shares that are widely held and actively traded.”⁴³ The Order Instituting Proceedings requested comment on whether the Proposal should include data demonstrating that the shares of the underlying ETP are “widely held and actively traded,” as required by Exchange rules.⁴⁴

One commenter stated that the Commission should wait and evaluate the market for spot bitcoin ETPs to determine the extent to which they are widely held and actively traded before approving options on the spot bitcoin ETPs.⁴⁵ The commenter stated that data indicated that, compared to when spot bitcoin ETPs were launched, investor demand for spot bitcoin ETPs had diminished, and that one market participant had expressed the view that the bitcoin ETP market should “settle and find its footing” before the Commission approves the listing of options on spot bitcoin ETPs.⁴⁶ In addition, the commenter urged the Commission to proceed cautiously

because “options on spot bitcoin ETPs will expose retail investors to a tremendous amount of risk.”⁴⁷ The commenter also stated that the approval of options on spot bitcoin ETPs could pose risks to the broader financial system because the Commission’s approval of spot bitcoin ETPs had deepened the connection between “volatile” cryptocurrencies and the traditional finance system.⁴⁸ The commenter stated that options on spot bitcoin ETPs “would further entangle the crypto industry with traditional finance” and aggravate the risks associated with crypto assets.⁴⁹

The Exchange has addressed comments regarding whether IBIT shares are widely held and actively traded.⁵⁰ In particular, the Exchange represented that “on May 13, 2024, IBIT’s total shares outstanding equaled 482,480,000. On May 13, 2024, IBIT’s total shares comprised approximately 4% of total underlying spot BTC liquidity. IBIT is the most liquid spot Bitcoin ETF and the 11th most liquid ETF in the U.S. by average volume (34,825,921 shares) and 18th largest by average notional (\$1,246,060,738). Of note, as of May 22, 2023, IBIT had approximately 193,956 shareholders.”⁵¹

ISE further represented that “the market capitalization for IBIT was 19,789,068 billion [sic], with an average daily volume (‘ADV’), for the preceding three months prior to August 7, 2024, of greater than 26 million shares.”⁵² In

⁴⁷ Better Markets Letter I at 1. *See also* letter from Benjamin L. Schiffman, Director of Securities Policy, Better Markets, Inc., dated September 13, 2024 (“Better Markets Letter II”). Better Markets Letter II reiterated the concerns that the commenter raised in Better Markets I and provided additional information regarding the volatility of bitcoin. Better Markets Letter II stated, for example, that in August 2024, bitcoin dropped 15% in a 24-hour period, a decline that, according to the commenter, affected more investors because of the Commission’s approval of bitcoin-based ETPs. *See* Better Markets Letter II at 2. The commenter stated that the risks to retail investors associated with options trading would be “compounded exponentially” because of the volatility of the crypto market and, further, that options on spot bitcoin-based exchange-traded products exacerbate the risks to retail investors of investing in bitcoin. *See* Better Markets Letter II at 3.

⁴⁸ *See* Better Markets Letter I at 4.

⁴⁹ Better Markets Letter I at 5. *See also* letter from anonymous commenter dated Apr. 15, 2024 (stating that the introduction of derivatives tied to the price of bitcoin would “spell disaster for the financial system and for global markets”).

⁵⁰ *See* ISE Letters I and II.

⁵¹ *See* ISE Letter I at 2. ISE stated that it obtained information regarding the number of shareholders by contacting broker-dealers and combining their reported shareholder counts. *See* ISE Letter I at notes 3 and 4.

⁵² ISE Letter II at 3. As of September 6, 2024, IBIT had net assets of \$20,083,776,594. *See* <https://www.ishares.com/us/products/333011/ishares-bitcoin-trust>.

³⁴ *See* Securities Exchange Act Release No. 99295 (Jan. 8, 2024), 89 FR 2321, 2334–35 (Jan. 12, 2024) (notice of filing of Amendment No. 1 to SR–Nasdaq–2023–016).

³⁵ *See* Amendment No. 5.

³⁶ *See* Notice, 89 FR at 5050.

³⁷ In approving this proposed rule change, the Commission has considered the proposed rule’s impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

³⁸ 15 U.S.C. 78f.

³⁹ 15 U.S.C. 78f(b)(5).

⁴⁰ In addition to the Proposal, the Order Instituting Proceedings sought comment on several other proposals to list and trade options on bitcoin ETPs. *See* Order Instituting Proceedings, 89 FR at 34294. *See also* ISE Letter I.

⁴¹ *See* letters from John C. Pickford, Susquehanna, dated Sept. 11, 2024; Steve Crutchfield, Head of Business Development, CTC, LLC, dated May 17, 2024; Congressman Mike Flood and Congressman Wiley Nickel, dated May 1, 2024; Joseph Ferrucci, dated Feb. 28, 2024; Benjamin Pincock, CIO, Method and Theory Capital Management, dated Feb. 19, 2024; Derek Jerina, dated Feb. 10, 2024; Xplorer Trading, dated Feb. 7, 2024; and an anonymous commenter, dated Jan. 21, 2024.

⁴² *See infra* notes 45–49 and accompanying text.

⁴³ *See* ISE Options 4, Section 3(a)(2).

⁴⁴ *See* Order Instituting Proceedings, 89 FR at 34294. *See also* ISE Options 4, Section 3(a).

⁴⁵ *See* letter from Benjamin L. Schiffman, Director of Securities Policy, Better Markets, Inc., dated May 21, 2024 (“Better Markets Letter I”) at 2.

⁴⁶ Better Markets Letter I at 2 and n. 17 (quoting Terrence Yang, managing director of Swan Bitcoin).

addition, ISE represented that on August 12, 2024, IBIT had 611,040,000 shares outstanding.⁵³ The Commission has reviewed the Exchange's analysis and publicly available data regarding IBIT. Based on this review of information provided by the Exchange and publicly available information—including information regarding the number of IBIT shareholders, the number of IBIT shares outstanding, the ADV of IBIT, and the net assets of IBIT—the Commission concludes that it is reasonable for the Exchange to determine that IBIT satisfies the requirement of ISE Options 4, Section 3(a)(2) that an underlying be widely held and actively traded. As stated above, one commenter suggested that fund outflows could indicate waning investor demand for spot bitcoin-based ETPs.⁵⁴ The Commission agrees that investor interest in IBIT may vary over time.⁵⁵ Nonetheless, the data discussed above indicate that it is reasonable to conclude that IBIT shares are widely held and actively traded.⁵⁶

With regard to comments regarding the Proposal's potential risks to retail investors, including concerns regarding the volatility of bitcoin,⁵⁷ existing rules governing broker-dealer conduct when dealing with retail customers would apply to the proposed IBIT options. For example, the Exchange's rules require its members to "exercise due diligence to learn the essential facts as to the Customer and his investment objectives and financial situation."⁵⁸ In fulfilling this obligation, the member must consider, among other things, a customer's investment objectives; employment status; estimated annual income; estimated net worth; and investment experience and knowledge.⁵⁹ Further, FINRA's heightened suitability requirements for options trading accounts require that a person recommending an opening position in any option contract have "a reasonable basis for believing, at the time of making the recommendation, that the customer has such knowledge and experience in financial matters that he may reasonably be expected to be capable of evaluating the risks of the recommended transaction, and is financially able to bear the risks of the

recommended position in the option contract."⁶⁰

The Commission acknowledges the comments regarding the potential impact of bitcoin ETP options on the traditional financial system. Pursuant to Section 19(b)(2) of the Exchange Act, however, the Commission must approve a proposed rule change filed by a national securities exchange if it finds that the proposed rule change is consistent with the applicable requirements of the Exchange Act.⁶¹ For the reasons discussed herein, the Commission finds that the proposed rule change satisfies the requirements of the Exchange Act, including the requirements in Section 6(b)(5) that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to remove impediments to and perfect the mechanism of a free and open market, and to protect investors and the public interest.

B. Position and Exercise Limits

The Order Instituting Proceedings also requested comment on whether the Proposal demonstrated that options on the bitcoin ETPs should be subject to the same position limits as options on stock, and whether the available supply in the markets for bitcoin should be considered in establishing position limits for options on the bitcoin ETPs.⁶²

Position and exercise limits serve as a regulatory tool designed to deter manipulative schemes and adverse market impact surrounding the use of options. Since the inception of standardized options trading, the options exchanges have had rules limiting the aggregate number of options contracts that a member or customer may hold or exercise. Options position and exercise limits are intended to prevent the establishment of options positions that can be used or might create incentives to manipulate or disrupt the underlying market to benefit the options position.⁶³ In addition, such limits serve to reduce the possibility of disruption in the options market itself, especially in illiquid classes.⁶⁴ As the Commission has previously recognized, markets with active and deep trading interest, as well as with broad public ownership, are more difficult to manipulate or disrupt than less active

and deep markets with smaller public floats.⁶⁵ The Commission also has recognized that position and exercise limits must be sufficient to prevent investors from disrupting the market for the underlying security by acquiring and exercising a number of options contracts disproportionate to the deliverable supply and average trading volume of the underlying security.⁶⁶ At the same time, the Commission has recognized that limits must not be established at levels that are so low as to discourage participation in the options market by institutions and other investors with substantial hedging needs or to prevent specialists and market-makers from adequately meeting their obligations to maintain a fair and orderly market.⁶⁷

The Exchange initially proposed to subject options on IBIT to the same position and exercise limit levels as other ETF options currently trading.⁶⁸ In Amendment No. 4, however, the Exchange proposed to provide position and exercise limits of 25,000 contracts for options on IBIT,⁶⁹ which are the lowest position and exercise limits to which other ETF options are subject. In proposing these position and exercise limits, the Exchange considered IBIT's market capitalization and ADV, and its prospective position and exercise limits in relation to other securities.⁷⁰ The Exchange stated that this analysis shows that options symbols with similar market capitalization and ADV to IBIT have a position and exercise limits in

⁶⁵ *Id.*

⁶⁶ See, e.g., Securities Exchange Act Release Nos. 21907 (Mar. 29, 1985), 50 FR 13440, 13441 (Apr. 4, 1985) (order approving File Nos. SR-CBOE-84-21, SR-Amex-84-30, SR-Phlx-84-25, and SR-PSE-85-1); and 40875 (Dec. 31, 1998), 64 FR 1842, 1843 (Jan. 12, 1999) (order approving File Nos. SR-CBOE-98-25; Amex-98-22; PCX-98-33; and Phlx-98-36).

⁶⁷ See *id.*

⁶⁸ See Notice, 89 FR at 5050.

⁶⁹ In Amendment No.4, the Exchange also clarified that its analysis in ISE Letter II applies to exercise limits as well as position limits.

⁷⁰ The Exchange represented that it aggregated market capitalization and volume data for securities that have defined position limits utilizing data from The Options Clearing Corporation. This pool of data took into consideration 3,984 options on single stock securities, excluding broad based ETFs. ISE aggregated the data based on market capitalization and ADV and grouped option symbols by position limit utilizing statistical thresholds for ADV and market capitalization that were one standard deviation above the mean for each position limit category (*i.e.*, 25,000, 50,000 to 65,000, 75,000, 100,000 to less than 250,000, 250,000 to 400,000, 450,000 to 1,000,000, and greater than or equal to 1,000,000). See ISE Letter II at 3–4. ISE Options 9, Section 13(d) establishes position limits for various options. For example, a 25,000-contract limit applies to options having an underlying security that does not meet the trading volume and outstanding shares requirements for a higher position limit. See *supra* note 22.

⁵³ See ISE Letter II at 5.

⁵⁴ See Better Markets Letter I at 2.

⁵⁵ For example, IBIT had net assets of \$20,083,776,594 as of September 6, 2024, and net assets of \$22,672,544,214 as of September 19, 2024. See *supra* note 52 and <https://www.ishares.com/us/products/333011/ishares-bitcoin-trust>.

⁵⁶ See *supra* notes 51–53 and accompanying text.

⁵⁷ See Better Markets Letter II at 2–3.

⁵⁸ See ISE Options 10, Section 6(b).

⁵⁹ See ISE Options 10, Section 6(b)(1).

⁶⁰ See FINRA Rule 2360(b)(19).

⁶¹ See Exchange Act Section 19(b)(2)(C), 15 U.S.C. 78s(b)(2)(C).

⁶² See Order Instituting Proceedings, 89 FR at 34294.

⁶³ See Securities Exchange Act Release No. 39489 (Dec. 24, 1997), 63 FR 276, 279 (Jan. 5, 1998) (order approving File No. SR-Cboe-97-11).

⁶⁴ *Id.*

excess of 400,000 options. Thus, according to the Exchange, this demonstrates that “the proposed 25,000 same side position limit for options on IBIT is extremely conservative relative to these options symbols which are a full standard deviation above the mean in comparison.”⁷¹

The Exchange also stated that it reviewed IBIT’s data relative to the market capitalization of the entire bitcoin market in terms of exercise risk and availability of deliverables.⁷² Utilizing data as of August 3, 2024, there were 19,737,193 bitcoins in circulation.⁷³ Using a price of \$57,000 per bitcoin, the market capitalization of bitcoin would be greater than \$1.125 trillion.⁷⁴ According to the Exchange, if a position limit of 400,000 options were considered, “the exercisable risk would represent only 6.6% of the outstanding shares of IBIT.”⁷⁵ The Exchange also stated that, with the proposed 25,000 position limit, the exercisable risk “only represents 0.4% of the outstanding shares of IBIT.”⁷⁶ Further, according to the Exchange, because IBIT has a creation and redemption process managed through the issuer, the exercisable risk for options on IBIT would be less than 0.01% of the market capitalization of all outstanding bitcoin.⁷⁷ The Exchange stated that, assuming a scenario where all options on IBIT shares were exercised given the proposed 25,000 per same side position limit, this would have a virtually unnoticed impact on the entire bitcoin market.⁷⁸ The Exchange also stated that “[t]his analysis demonstrates that the proposed 25,000 per same side position limit is also “extremely conservative and more than appropriate for options on IBIT.”⁷⁹

In addition, the Exchange compared the proposed position limit to position limits for derivative products regulated by the Commodity Futures Trading Commission (“CFTC”). Specifically, the Exchange examined the equivalent bitcoin futures position limits, and, specifically, the CME bitcoin futures contract, which has a position limit of 2,000 futures.⁸⁰ Based on this analysis, the Exchange believes that a position limit of 176,338 contracts for IBIT options would be equivalent to the 2,000-contract notional position limit

for CME bitcoin futures.⁸¹ Stated another way, the Commission estimates that the proposed position limit of 25,000 contracts for IBIT options is roughly equivalent to a position limit of 280 bitcoin futures contracts. In analyzing the proposed position and exercise limits, ISE also considered the supply of IBIT and the number of market participants that would be required to exercise their positions in unison to place the underlying asset under stress.⁸² ISE concluded that with a position limit of 25,000 contracts on the same side of the market and 611,040,000 shares of IBIT outstanding, 244 market participants would have to simultaneously exercise their positions to place IBIT under stress.⁸³ ISE further stated that, historically, from observation, it appears that no more than five market participants holding positions in a security have exercised their options at the same time.⁸⁴

Option position limits are determined based on six-month trading volume in the underlying security or six-month trading volume and number of shares outstanding of the underlying security.⁸⁵ The Exchange stated that position limits must balance concerns regarding mitigating potential manipulation and the cost of inhibiting potential hedging activity that could be used for legitimate economic purposes, and to achieve such balance, options on IBIT would be subject to the 25,000-option contract limit.⁸⁶ The Commission finds that the proposed position and exercise limits are consistent with the Act, and in particular, with the requirements in Section 6(b)(5) that the rules of a national securities exchange designed to prevent fraudulent and manipulative acts and practices and to protect investors and the public interest. As discussed above, the Commission has recognized that position and exercise limits must be sufficient to prevent investors from disrupting the market for the underlying security by acquiring and exercising a number of options contracts disproportionate to the deliverable supply and average trading volume of the underlying security.⁸⁷ In addition, the Commission has stated previously that rules regarding position

and exercise limits are intended to prevent the establishment of options positions that can be used or might create incentives to manipulate or disrupt the underlying market so as to benefit the options position.⁸⁸ Based on its review of the data and analysis provided by the Exchange, the Commission concludes that the proposed position and exercise limits satisfy these objectives. Specifically, the Commission has considered and reviewed the Exchange’s analysis that the exercisable risk associated with a position limit of 25,000 contracts represented only 0.4% of the outstanding shares of IBIT.⁸⁹ The Commission also has considered and reviewed the Exchange’s statement that with a position limit of 25,000 contracts on the same side of the market and 611,040,000 shares of IBIT outstanding, 244 market participants would have to simultaneously exercise their positions to place IBIT under stress.⁹⁰ Based on the Commission’s review of this information and analysis, the Commission concludes that the proposed position and exercise limits are designed to prevent investors from disrupting the market for the underlying security by acquiring and exercising a number of options contracts disproportionate to the deliverable supply and average trading volume of the underlying security, and to prevent the establishment of options positions that can be used or might create incentives to manipulate or disrupt the underlying market so as to benefit the options position.

C. Surveillance

Lastly, in the Order Instituting Proceedings, the Commission asked whether the Proposal should include information regarding how the Exchange would obtain information concerning trading in the bitcoin ETPs from the exchanges where the bitcoin ETPs trade. In its letter to the Commission, the Exchange represented that it “would implement any new surveillance procedures it deemed necessary to effectively monitor the trading of options on Bitcoin ETPs.”⁹¹ In Amendment No. 5 to the Proposal, ISE provided additional detail regarding the surveillance procedures that will apply to IBIT options. As described more fully above, the Exchange will apply its existing options surveillance

⁷¹ See ISE Letter II at 4.

⁷² See *id.*

⁷³ See *id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ See *id.*

⁷⁷ See *id.*

⁷⁸ See *id.*

⁷⁹ *Id.*

⁸⁰ See *id.*

⁸¹ The Exchange multiplied the 2,000-contract limit by a multiplier of five, resulting in \$550 million of notional value for bitcoin futures. See ISE Letter II for a detailed description of the Exchange’s methodology.

⁸² See *id.* at 5.

⁸³ See *id.*

⁸⁴ See *id.*

⁸⁵ See *supra* note 19 and accompanying text.

⁸⁶ See ISE Letter II at 3.

⁸⁷ See *supra* note 66 and accompanying text.

⁸⁸ See Securities Exchange Act Release No. 57352 (Feb. 19, 2008), 73 FR 10076, 10080 (Feb. 25, 2008) (order approving File No. SR-Cboe-2008-07).

⁸⁹ See ISE Letter II at 4.

⁹⁰ See *id.* at 5.

⁹¹ ISE Letter I at 7.

procedures to IBIT options.⁹² The Exchange states that it market surveillance staff will have access to the surveillances conducted by Nasdaq with respect to IBIT and will review activity in IBIT when conducting surveillances for market abuse or manipulation in options on IBIT.⁹³ Additionally, the Exchange states that it is a member of ISG, whose members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets.⁹⁴ CME also is a member of ISG. In approving the Bitcoin ETPs, the Commission concluded that:

fraud or manipulation that impacts prices in spot bitcoin markets would likely similarly impact CME bitcoin futures prices. And because the CME's surveillance can assist in detecting those impacts on CME bitcoin futures prices, the Exchanges' comprehensive surveillance-sharing agreement with the CME—a U.S. regulated market whose bitcoin futures market is highly correlated to spot bitcoin—can reasonably be expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of [the Bitcoin ETPs].⁹⁵

Together, these surveillance procedures should allow the Exchange to investigate suspected manipulations or other trading abuses in IBIT options.

D. Additional Changes

The proposed changes to update the name of the ETFS Gold Trust to the Aberdeen Standard Physical Gold Trust and to correct the cross-references in ISE Options 4, Section 4(g) will protect investors and the public interest by helping to ensure that the Exchange's rules remain accurate and up-to-date.

IV. Solicitation of Comments on Amendment Nos. 4 and 5 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment Nos. 4 and 5 are 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-ISE-2024-03 on the subject line.

⁹² The Exchange states that its surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (e.g., spoofing, marking the close, ping, phishing). See Amendment No. 5.

⁹³ See *id.*

⁹⁴ See *id.*

⁹⁵ See Bitcoin ETP Order, 89 FR at 3010–11.

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-ISE-2024-03. 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-ISE-2024-03 and should be submitted on or before October 17, 2024.

V. Accelerated Approval of Amendment Nos. 4 and 5

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act, for approving Amendment Nos. 4 and 5 prior to the 30th day after the date of publication of notice of Amendment No. 3 in the **Federal Register**. Amendment No. 4 amends the Proposal to establish position and exercise limits of 25,000 contract for the proposed IBIT options, instead of the same position and exercise limits as other options currently trading. The Exchange stated that some commodity-based ETPs currently have position and exercise limits of 250,000 contracts.⁹⁶ As described above, ISE provided data and

⁹⁶ See ISE Letter II at 6 (stating that the SPDR Gold Shares ETF and the iShares Silver Trust ETF have position limits of 250,000 contracts).

analysis supporting the proposed position and exercise limits and stated, among other things, that the proposed position and exercise limits would represent 0.4% of the outstanding shares of IBIT.⁹⁷ The Commission concludes that proposed position and exercise limits are designed to minimize the potential for manipulations or disruptions of the underlying market.⁹⁸ Amendment No. 5 describes in greater detail the surveillance procedures that will apply to IBIT options. The additional information regarding these procedures assists the Commission in evaluating the Proposal and determining that the Proposal is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange, as discussed above. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,⁹⁹ to approve the proposed rule change, as modified by Amendment Nos. 4 and 5, on an accelerated basis.

VI. Conclusion

For the reasons set forth above, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1, 4, and 5, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6(b)(5) of the Act.¹⁰⁰

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,¹⁰¹ that the proposed rule change (SR-ISE-2024-03), as modified by Amendment Nos. 1, 4, and 5, be, and is hereby, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰²

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-22024 Filed 9-25-24; 8:45 am]

BILLING CODE 8011-01-P

⁹⁷ See ISE Letter II at 4.

⁹⁸ The Commission recognizes that position limits should not be established at levels that are so low as to discourage participation in the options market by institutions and other investors with substantial hedging needs or to prevent specialists and market makers from adequately meeting their obligations to maintain a fair and orderly market. See, e.g., Securities Exchange Act Release Nos. 21907 (Mar. 29, 1985), 50 FR 13440 (Apr. 4, 1985) (order approving File Nos. SR-CBOE-84-21, SR-Amex-84-30, SR-Phlx-84-25, and SR-PSE-85-1); 40875 (Dec. 31, 1998), 64 FR 1842, 1843 (Jan. 12, 1999) (order approving File Nos. SR-CBOE-98-25; Amex-98-22; PCX-98-33; and Phlx-98-36). The Commission finds that the proposed position and exercise limits are consistent with these objectives.

⁹⁹ 15 U.S.C. 78s(b)(2).

¹⁰⁰ 15 U.S.C. 78f(b)(5).

¹⁰¹ 15 U.S.C. 78s(b)(2).

¹⁰² 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101127; File No. SR–NYSEARCA–2024–80]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Options Proprietary Market Data Fee Schedule

September 20, 2024.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”)² and Rule 19b–4 thereunder,³ notice is hereby given that, on September 16, 2024, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Options Proprietary Market Data Fee Schedule (“Fee Schedule”) applicable to various market data products. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule applicable to various

market data products. More specifically, the Exchange proposes to adopt a free trial program for NYSE Arca options market data products, effective September 16, 2024.⁴

The Exchange proposes a one-month free trial for any firm that subscribes to a particular NYSE Arca options market data product for the first time. As proposed, a first-time subscriber would be any firm that has not previously subscribed to a particular NYSE Arca options market data product listed on the Fee Schedule. As proposed, a first-time subscriber of a particular NYSE Arca options market data product would not be charged the Access Fee, Non-Display Fee, any applicable Professional and Non-Professional User Fee, and Redistribution Fee for that product for one calendar month. For example, a firm that currently subscribes to the Arca Options Complex would be eligible to receive a free one-month trial of the Arca Options Product, whether in a display-only format or for non-display use. On the other hand, a firm that currently pays an Access Fee and receives the Arca Options Product for non-display use would not be eligible to receive a free one-month trial of the Arca Options Product in a display-only format. The proposed free trial would be for the first full calendar month following the date a subscriber is approved to receive trial access to the particular NYSE Arca options market data product. The Exchange would provide the one-month free trial for each particular product to each subscriber once.

The Exchange believes that providing a one-month free trial to Exchange real-time market data products listed on the Fee Schedule would enable potential subscribers to determine whether a particular NYSE Arca options market data product provides any benefit to their business models before fully committing to expend development and implementation costs related to the receipt of that product, and is intended to encourage increased use of the Exchange’s market data products by defraying some of the development and implementation costs subscribers would ordinarily have to expend before using a product. The Exchange notes that other exchanges have similar free trial programs.⁵

⁴ The Exchange originally filed to amend the Fee Schedule on September 3, 2024 (SR–NYSEARCA–2024–73). SR–NYSEARCA–2024–73 was subsequently withdrawn and replaced by this filing.

⁵ See The Nasdaq Stock Market LLC (“Nasdaq”) Equity 7 Pricing Schedule, Section 112(b)(1) and Cboe Exchange, Inc. Fees Schedule.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,⁶ in general, and furthers the objectives of Section 6(b)(4),⁷ in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data. In addition, the Exchange believes that the proposed rule change is consistent with Section 11(A) of the Act as it supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets, and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities.⁸

The Exchange believes that the proposed rule change to provide Exchange real-time market data products listed on the Fee Schedule to new customers free-of-charge for their first subscription month is reasonable because it would allow vendors and subscribers to become familiar with the feeds and determine whether they suit their needs without incurring fees. It is also intended to incentivize Redistributors to enlist more subscribers to subscribe to Exchange market data products to broaden the products’ distribution. Making a new market data product available for free for a trial period is consistent with offerings of other exchanges. As noted above, other exchanges offer new subscribers a similar waiver of market data fees.⁹

The Exchange believes the proposal to provide Exchange real-time market data products listed on the Fee Schedule to new customers free-of-charge for their first subscription month is equitable because the free trial would apply to any first-time subscriber, regardless of the use they plan to make of the feed. As proposed, any first-time subscriber would not be charged the Access Fee, Non-Display Fee, any applicable Professional and Non-Professional User Fee, or Redistribution Fee for any of the real-time market data products listed on the Fee Schedule for one calendar month. The Exchange believes it is equitable to restrict the availability of this one-month free trial to customers that have not previously subscribed to any Exchange real-time market data product, since customers who are current or previous subscribers are

⁶ 15 U.S.C. 78f.

⁷ 15 U.S.C. 78f(b)(4).

⁸ 15 U.S.C. 78k–1.

⁹ See note 5, *supra*.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

already familiar with the products and whether they would suit their needs.

The Exchange believes that the proposed rule change to provide for a one-month free trial period to test is not unfairly discriminatory because the financial benefit of the fee waiver would be available to all firms subscribing to the Exchange's real-time market data products for the first time on a free-trial basis. The Exchange believes there is a meaningful distinction between customers that are subscribing to a market data product for the first time, who may benefit from a period within which to set up and test use of the product before it becomes fee liable, and users that are already receiving the Exchange's market data products. The Exchange believes that the limited period of the free trial would not be unfairly discriminatory to other users of the Exchange's market data products because it is designed to provide a reasonable period of time to set up and test a new market data product. The Exchange further believes that providing a free trial for one calendar month would ease administrative burdens for data recipients to subscribe to a new data product and eliminate fees for a period before such users are able to derive any benefit from the data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment, and its ability to price these data products is constrained by competition among exchanges that offer similar data products to their customers. The Exchange believes that the proposed free trial program does not put any market participants at a relative disadvantage compared to other market participants. As discussed, the proposed trial would apply to first time subscribers on an equal and non-discriminatory basis. Further, the Exchange believes that the proposed program does not impose a burden on competition on other SROs that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposal would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges are free to lower their prices or provide a free trial to better compete with the Exchange's offering. Indeed, other national securities exchanges already

offer similar free trial programs today.¹⁰ The proposed rule change is also designed to enhance competition by providing an incentive to Redistributors to enlist new subscribers to subscribe to Exchange's real-time market data products.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A)¹¹ of the Act and paragraph (f) [sic] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEARCA-2024-80 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to file number SR-NYSEARCA-2024-80. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent

amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEARCA-2024-80 and should be submitted on or before October 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-22020 Filed 9-25-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101126; File No. SR-NYSE-2024-18]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Withdrawal of a Proposed Rule Change To Amend Section 102.06 of the NYSE Listed Company Manual To Provide That a Special Purpose Acquisition Company Can Remain Listed Until Forty-Two Months From Its Original Listing Date if it Has Entered Into a Definitive Agreement With Respect to a Business Combination Within Three Years of Listing

September 20, 2024.

On March 27, 2024, the New York Stock Exchange LLC ("Exchange" or "NYSE") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act")¹ and Rule 19b-4

¹⁰ See note 5, *supra*.

¹¹ 15 U.S.C. 78s(b)(3)(A).

¹² 17 CFR 200.30-3(a)(12).

¹³ 15 U.S.C. 78s(b)(1).

thereunder,² a proposed rule change to amend Section 102.06 of the NYSE Listed Company Manual to provide that a special purpose acquisition company can remain listed until forty-two months from its original listing date if it has entered into a definitive agreement with respect to a business combination within three years of listing. The proposed rule change was published for comment in the **Federal Register** on April 10, 2024.³

On May 22, 2024, pursuant to Section 19(b)(2) of the Exchange Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ On July 9, 2024, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act⁶ to determine whether to approve or disapprove the proposed rule change.⁷

On September 10, 2024, the Exchange withdrew the proposed rule change (SR-NYSE-2024-18).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-22022 Filed 9-25-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101125; File No. 4-757]

Joint Industry Plan; Notice of Designation of a Longer Period for Commission Action on a Proposed National Market System Plan Regarding Consolidated Equity Market Data

September 20, 2024.

On October 23, 2023, Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Cboe Exchange, Inc., Investors Exchange LLC, Long Term Stock Exchange, Inc., MEMX LLC,

MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq ISE, LLC, Nasdaq PHLX LLC, Nasdaq Stock Market LLC, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., NYSE National, Inc., and the Financial Industry Regulatory Authority, Inc. filed with the Securities and Exchange Commission (“Commission”), pursuant to section 11A of the Securities Exchange Act of 1934¹ and Rule 608 of Regulation National Market System (“Regulation NMS”) thereunder,² a proposed new single national market system plan governing the public dissemination of real-time consolidated equity market data for national market system stocks (the “CT Plan”). The proposed CT Plan was published for comment in the **Federal Register** on January 25, 2024.³

On April 23, 2024, the Commission instituted proceedings pursuant to Rule 608(b)(2)(i) of Regulation NMS,⁴ to determine whether to approve or disapprove the proposed CT Plan or to approve the proposed CT Plan with any changes or subject to any conditions the Commission deems necessary or appropriate.⁵ On July 11, 2024, pursuant to Rule 608(b)(2)(i) of Regulation NMS,⁶ the Commission extended the period within which to conclude proceedings regarding the proposed CT Plan to 240 days from the date of publication of the Notice.⁷

Rule 608(b)(2)(ii) of Regulation NMS provides that the time for conclusion of proceedings to determine whether a national market system plan or proposed amendment should be disapproved may be extended for an additional period up to 60 days (up to 300 days from the date of notice publication) if the Commission determines that a longer period is appropriate and publishes the reasons for such determination or the plan

participants consent to the longer period.⁸ The 240th day after publication of the Notice for the proposed CT Plan is September 21, 2024. The Commission is extending this 240-day period.

The Commission finds that it is appropriate to designate a longer period within which to conclude proceedings regarding the proposed CT Plan so that it has sufficient time to consider important issues raised by the proposed CT Plan and the comments received.⁹ Accordingly, pursuant to Rule 608(b)(2)(ii) of Regulation NMS,¹⁰ the Commission designates November 20, 2024, as the date by which the Commission shall conclude the proceedings to determine whether to approve or disapprove the proposed CT Plan or to approve the proposed CT Plan with any changes or subject to any conditions the Commission deems necessary or appropriate (File No. 4-757).

By the Commission.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-22001 Filed 9-25-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101120; File No. SR-CBOE-2024-043]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Rules To Permit the Listing and Trading of Options Based on 1/100 of the Value of the Nasdaq-100 Index® (“Nasdaq-100”)

September 20, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 18, 2024, Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section

¹ 15 U.S.C. 78k-1.

² 17 CFR 242.608.

³ See Joint Industry Plan; Notice of Filing of a National Market System Plan Regarding Consolidated Equity Market Data, Securities Exchange Act Release No. 99403 (Jan. 19, 2024), 89 FR 5002 (Jan. 25, 2024) (“Notice”).

⁴ 17 CFR 242.608(b)(2)(i).

⁵ See Joint Industry Plan; Order Instituting Proceedings to Determine Whether to Approve or Disapprove a National Market System Plan Regarding Consolidated Equity Market Data, Securities Exchange Act Release No. 100017 (Apr. 23, 2024), 89 FR 33412 (Apr. 29, 2024) (“OIP”). Comments received in response to the OIP can be found on the Commission’s website at: <https://www.sec.gov/comments/4-757/4-757.htm>.

⁶ 17 CFR 242.608(b)(2)(i).

⁷ See Joint Industry Plan; Notice of Designation of a Longer Period for Commission Action on a Proposed National Market System Plan Regarding Consolidated Equity Market Data, Securities Exchange Act Release No. 100500 (Jul. 11, 2024), 89 FR 58235 (Jul. 17, 2024).

⁸ 17 CFR 242.608(b)(2)(ii).

⁹ Comments received in response to the Notice can be found on the Commission’s website at: <https://www.sec.gov/comments/4-757/4-757.htm>.

¹⁰ 17 CFR 242.608(b)(2)(ii).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 99906 (Apr. 4, 2024), 89 FR 25291 (“Notice”).

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 100220 (May 22, 2024), 89 FR 46527 (May 29, 2024).

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 100480 (July 9, 2024), 89 FR 57436 (July 15, 2024) (“OIP”). Comments received in response to the OIP can be found on the Commission’s website at: <https://www.sec.gov/comments/sr-nyse-2024-18/srnyse202418.htm>.

⁸ 17 CFR 200.30-3(a)(12).

19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend the Exchange's rules to permit the listing and trading of options based on 1/100 of the value of the Nasdaq-100 Index[®] ("Nasdaq-100"). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), 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 purpose of this proposed rule change is to amend certain rules to permit the Exchange to list and trade index options on Nasdaq 100 Micro Index Options ("XND"). The XND options contract is the same in all respects as the current Nasdaq-100 Index options ("NDX")⁵ contract listed on the Exchange, except that it is based on 1/100 of the value of the Nasdaq-100 Index, and will be P.M.-Settled with an exercise settlement value based on the closing index value of the Nasdaq-100 Index on the day of expiration.⁶ The

Exchange believes that the proposed contract will be valuable for retail and other investors that wish to trade micro options on the Nasdaq-100 Index. Today, Nasdaq Phlx LLC ("Phlx")⁷ and Nasdaq ISE, LLC ("ISE")⁸ have approval to list and trade XND options. The proposed rules to list and trade XND options on the Exchange are substantially similar to those of Phlx and ISE.

Nasdaq-100 Index

The Nasdaq-100 Index is a modified market capitalization-weighted index that includes 100 of the largest non-financial companies listed on The Nasdaq Stock Market LLC ("Nasdaq"), based on market capitalization.⁹ It does not contain securities of financial companies, including investment companies. Security types generally eligible for the Nasdaq-100 Index include common stocks, ordinary shares, American Depository Receipts, and tracking stocks. Security or company types not included in the Nasdaq-100 Index are closed-end funds, convertible debentures, exchange traded funds, limited liability companies, limited partnership interests, preferred stocks, rights, shares or units of beneficial interest, warrants, units and other derivative securities.¹⁰

XND Options Contract

Currently, the Exchange is permitted to list NDX options that are based on the full value of the Nasdaq-100 Index. The Exchange now proposes to amend its Rules to permit the listing of a new micro option contract based on this index. XND options will trade independently of and in addition to NDX options, and the XND options will be subject to the same rules that presently govern the trading of index options based on the Nasdaq-100 Index, including sales practice rules, margin requirements, trading rules, and position and exercise limits. Similar to NDX, XND options will be European-style and cash-settled, and will have a contract multiplier of 100. The contract specifications for XND options will

mirror in all respects those of the NDX options contract already permitted to be listed on the Exchange, except that the Exchange proposes that XND options will be based on 1/100 of the value of the Nasdaq-100 Index, and will be P.M.-settled pursuant to proposed Rule 4.13, Interpretation and Policy .14. The Exchange also proposes to amend Rule 4.13(a)(4) to permit options on the Nasdaq 100 Micro Index to trade a.m.-settled.

Pursuant to Rule 4.13(e), the Exchange would be permitted to open for trading Weekly Expirations on XND, as a broad-based index and part of the Nonstandard Expirations Program, to expire on any Monday, Tuesday, Wednesday, Thursday or Friday (other than the third Friday-of-the-month or days that coincide with an EOM expiration). ISE's rules similarly permit XND to expire on any Monday, Tuesday, Wednesday, Thursday or Friday.¹¹ Weekly Expirations in XND would be subject to all provisions of Rule 4.13 and treated the same as options on the same underlying index that expire on the third Friday of the expiration month; provided, however, that Weekly Expirations shall be P.M.-settled and new series in Weekly Expirations may be added up to and including on the expiration date for an expiring Weekly Expiration. The maximum number of expirations that may be listed for each Weekly Expiration (*i.e.*, a Monday expiration, Tuesday expiration, Wednesday expiration, Thursday expiration, or Friday expiration, as applicable) in a given class is the same as the maximum number of expirations permitted in Rule 4.13(a)(2) for standard options on the same broad-based index.

Further, the Exchange may open for trading EOMs on any broad-based index eligible for standard options trading to expire on the last trading day of the month. EOMs shall be subject to all provisions of Rule 4.13 and treated the same as options on the same underlying index that expire on the third Friday of the expiration month; provided, however, that EOMs shall be P.M.-settled and new series in EOMs may be added up to and including on the expiration date for an expiring EOM.¹² Today, XND options on Phlx¹³ and ISE¹⁴ are part of the Nonstandard Program.

⁷ See Securities Exchange Act Release No. 98451 (September 20, 2023), 88 FR 66088 (September 26, 2023) (SR-Phlx-2023-07) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Make Permanent Certain P.M.-Settled Pilots).

⁸ See Securities Exchange Act Release No. 98886 (November 8, 2023), 88 FR 78417 (November 15, 2023) (SR-ISE-2023-24) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Permit the Listing and Trading of XND Options).

⁹ The Nasdaq-100 Index is a broad-based index. See Rule 4.10.

¹⁰ A description of the Nasdaq-100 Index is available on Nasdaq's website at https://indexes.nasdaqomx.com/docs/methodology_NDX.pdf.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

⁵ See Rule 4.13(a)(3).

⁶ In addition to the current Nasdaq-100 Index value, Nasdaq disseminates an index value for XND that is 1/100 of the value of the Nasdaq-100 Index.

¹¹ See ISE Rules, Options 4A, Section 12, Supplementary Material .07.

¹² XND is a broad-based index.

¹³ See Phlx Options 4A, Section 12(b)(5).

¹⁴ See ISE Rules, Options 4A, Section 12, Supplementary Material .07.

The Exchange does not believe that the introduction of a new P.M.-settled Nasdaq-100 Index contract will cause any market disruptions, as noted herein, because the proposed rule change is substantially similar in all material respects to a proposal submitted by Phlx¹⁵ that was previously approved by the Commission, as well as a proposal submitted by ISE¹⁶ that was subject to Commission review. The Exchange will monitor for any disruptions caused by P.M.-settlement of the proposed XND options contract or the development of any factors that could cause such disruptions. P.M.-settled options predominate in the over-the-counter (“OTC”) market, and the Exchange is not aware of any adverse effects in the OTC market attributable to the P.M.-settlement feature. The Exchange is merely proposing to offer a P.M.-settled product in an exchange environment, which offers the additional benefits of added transparency, price discovery, and stability.

Additionally, the Exchange proposes to amend Rule 4.12(c) to add the Nasdaq 100 Mirco [*sic*] Index to the table regarding reporting authorities for indexes. The Exchange notes the Nasdaq 100 Index currently has the same reporting authority, *i.e.*, Nasdaq, Inc.

Trading Hours, Minimum Increments, Expirations and Strike Prices

XND options will be available for trading during the Exchange’s standard trading hours for index options, *i.e.*, from 9:30 a.m. to 4:15 p.m. (Eastern time),¹⁷ except that that on the last trading day, transactions in expiring p.m.-settled broad-based index options may be effected on the Exchange between the hours of 9:30 a.m. (Eastern time) and 4 p.m. (Eastern time).¹⁸ The trading hours for XND options will be the same as the trading hours for options on Nasdaq-100 Index.

XND options will be permitted to trade with a minimum trading increment of \$0.01 for all options series¹⁹ similar to Phlx²⁰ and ISE.²¹

The Exchange proposes to amend Rule 5.4(a) to state that for so long as Invesco QQQ Trust Series 1 (“QQQ”) options participate in the Penny Interval Program, the minimum increments for XND options shall be the same as QQQ for all options series (including LEAPS), which shall be \$0.01 for options for all other series.

The Exchange proposes that XND options will have monthly expiration dates on the third Friday of each month (*i.e.*, Expiration Friday), and the Exchange proposes to list XND options in expiration months consistent with those of other index option products available on the Exchange.²² In addition, the Exchange may list long-term index options series (“LEAPS”) that expire from twelve (12) to one-hundred eighty (180) months from the date of issuance.²³ There may be up to ten (10) expiration months, none further out than one-hundred eighty (180) months. Continuity Rules shall not apply to such options series until the time to expiration is less than 270 days.²⁴ Further, the Exchange proposes to add “Nasdaq 100 Micro Index” to the list of stock indices for which reduced-value LEAPS are approved for trading on the Exchange, set forth in Rule 4.13(b)(2)(A). Pursuant to Rule 4.13(b)(2)(B), reduced-value LEAPS may expire at six-month intervals. When a new expiration month is listed, series may be near or bracketing the current index value. Additional series may be added when the value of the underlying index increases or decreases by 10 to 15%. XND options would also be eligible to be added to the Short Term Option Series Program (“Weeklies”) and/or Quarterly Options Series Program (“Quarterlies”) if designated by the Rules 4.13(a)(2)(A) and (a)(2)(B), respectively.

Further, as noted herein, the Exchange proposes to permit XND options to be listed and traded in accordance with the Nonstandard Expirations Program, which permits broad-based indexes to list standard options trading to expire on any Monday, Tuesday, Wednesday, Thursday, or Friday (other than the third Friday-of-the-month or days that coincide with an EOM expiration). Weekly Expirations would be subject to all provisions of Rule 4.13 and would be treated the same as options on the same underlying index that expire on the third Friday of the expiration month. New series in Weekly Expirations could be added up to and including on the

expiration date for an expiring Weekly Expiration. The maximum number of expirations that could be listed for each Weekly Expiration (*i.e.*, a Monday expiration, Tuesday expiration, Wednesday expiration, Thursday expiration, or Friday expiration, as applicable) in a given class would be the same as the maximum number of expirations permitted for standard options on the same broad-based index.²⁵ Further, the Exchange could open for trading EOMs on any broad-based index eligible for standard options trading to expire on last trading day of the month. EOMs would be subject to all provisions of Rule 4.13 and treated the same as options on the same underlying index that expire on the third Friday of the expiration month. However, the EOMs would be P.M.-settled and new series in EOMs could be added up to and including on the expiration date for an expiring EOM.²⁶ Today, XND options on Phlx²⁷ and ISE²⁸ are part of the Nonstandard Program of each of those exchanges.

Generally, pursuant to Rule 4.13, Interpretation and Policy .01, except as provided in Rule 4.13, Interpretation

²⁵ Weekly Expirations need not be for consecutive Monday, Tuesday, Wednesday, Thursday, or Friday expirations as applicable; however, the expiration date of a non-consecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. Weekly Expirations that are first listed in a given class may expire up to four weeks from the actual listing date. If the Exchange lists EOMs and Weekly Expirations as applicable in a given class, the Exchange will list an EOM instead of a Weekly Expiration that expires on the same day in the given class. Other expirations in the same class are not counted as part of the maximum number of Weekly Expirations for an applicable broad-based index class. If the Exchange is not open for business on a respective Monday, the normally Monday expiring Weekly Expirations will expire on the following business day. If the Exchange is not open for business on a respective Tuesday, Wednesday, Thursday, or Friday, the normally Tuesday, Wednesday, Thursday, or Friday expiring Weekly Expirations will expire on the previous business day. If two different Weekly Expirations would expire on the same day because the Exchange is not open for business on a certain weekday, the Exchange will list only one of such Weekly Expirations. See Rule 4.13(e)(1).

²⁶ The maximum number of expirations that may be listed for EOMs in a given class is the same as the maximum number of expirations permitted in Rule 4.13(a)(2) for standard options on the same broad-based index. EOM expirations need not be for consecutive end of month expirations; however, the expiration date of a non-consecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. EOMs that are first listed in a given class may expire up to four weeks from the actual listing date. Other expirations in the same class are not counted as part of the maximum numbers of EOM expirations for a broad-based index class. See Rule 4.13(e)(2).

²⁷ See Phlx Options 4A, Section 12(b)(5).

²⁸ See ISE Rules, Options 4A, Section 12, Supplementary Material .07.

¹⁵ See Securities Exchange Act Release No. 98451 (September 20, 2023), 88 FR 66088 (September 26, 2023) (SR-Phlx–2023–07) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Make Permanent Certain P.M.-Settled Pilots).

¹⁶ See Securities Exchange Act Release No. 98886 (November 8, 2023), 88 FR 78417 (November 15, 2023) (SR-ISE–2023–24) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Permit the Listing and Trading of XND Options).

¹⁷ See Rule 5.1(b)(2).

¹⁸ See Rule 4.13(e)(3).

¹⁹ This is the case as long as QQQ options (“QQQ”) participate in the Penny Interval Program.

²⁰ See Phlx Supplementary Material .03 to Options 3, Section 3.

²¹ See ISE Rules, Options 3, Section 3.

²² See Rule 4.13(a)(2).

²³ See Rule 4.13(b).

²⁴ See Rule 5.52(d)(2).

and Policy .01(h), the exercise (strike) price intervals will be no less than \$5, provided that, in the case of certain classes of index options noted in Rule 4.13, Interpretation and Policy .01(a), the Exchange may determine to list strike prices at no less than \$2.50 intervals. The Exchange proposes to amend Rule 4.13, Interpretation and Policy .01(a) add XND options to the list of classes where strike price intervals of no less than \$2.50 are generally permitted and note, “if the strike price is less than \$200.”²⁹ Further, the Exchange proposes to amend Rule 4.13, Interpretation and Policy .01(h) which currently provides that the Exchange may also list series at \$1 strike intervals for Mini-Nasdaq-100 Index (“MNX” or “Mini-NDX”). Specifically, the Exchange proposes to amend Rule 4.13, Interpretation and Policy .01(h) to adopt the same strike price intervals for XND options as are listed for XND options on ISE³⁰ and currently approved for MNX options within Rule 4.13, Interpretation and Policy .01(h). Thus, notwithstanding 4.13, Interpretation and Policy .01(a), the interval between strike prices of series of XND options may be \$1 (or greater), subject to the conditions described in Rule 4.13, Interpretation and Policy .01(h). The Exchange will not list LEAPS on XND options at intervals less than \$2.50. If the Exchange determines to add XND options to the Weeklies or Quarterlies programs such options will be listed with expirations and strike prices described in Rule 4.13, Interpretation and Policy .01(h).

Position and Exercise Limits; Margin

The Exchange proposes to amend Rule 8.31(a). As with NDX, in determining compliance with Rule 8.31 (Position Limits for Broad-Based Index Options), there will be no position limits for broad-based index option contracts in the XND class.³¹ Since the Exchange is proposing to list a micro index contract that is based on 1/100 of the value of the Nasdaq-100 Index, Rule 8.31(f) would apply. The Exchange proposes to apply broad-based index margin requirements for the purchase and sale of XND options that are the same as margin requirements currently in place for NDX options.

²⁹ Reduced-value Nasdaq 100 Index options are currently included in the list of classes where strike price intervals of no less than \$2.50 are generally permitted. As part of the proposed changes, the Exchange also proposes to add the same “if the strike price is less than \$200” language to the Reduced-value Nasdaq 100 Index, as this language was inadvertently omitted.

³⁰ See ISE Rules, Options 4A, Section 12(c)(5).

³¹ See proposed changes to Rule 8.31(a).

Further, the Exchange proposes to amend Rule 8.35(b) to add XND to the list of broad-based FLEX index options for which there are no position limits.

In addition, there would be no exercise limits for XND. As such, the Exchange proposes to amend Rule 8.42(b) to include XND in the list of broad-based index options for which there are no exercise limits and Rule 8.42(g) to include XND in the list broad-based FLEX index options for which there are no exercise limits. The same rules for position and exercise limits to XND options on ISE.³²

Surveillance and Capacity

The Exchange represents that it has sufficient capacity to handle additional quotations and message traffic associated with the proposed listing and trading of XND options. Further, the Exchange has analyzed its capacity and represents that it believes the Exchange and the Options Price Reporting Authority (“OPRA”) have the necessary systems capacity to handle any additional traffic associated with the listing of the maximum number nonstandard expirations permitted pursuant to Rule 4.13(e).

Index options are integrated into the Exchange’s existing surveillance system architecture, as well as the Financial Industry Regulatory Authority’s (FINRA) (which performs certain regulatory services for the Exchange pursuant to a regulatory services agreement), and are thus subject to the relevant surveillance processes. The Exchange represents that it has adequate surveillance procedures to monitor trading in XND options thereby aiding in the maintenance of a fair and orderly market.

The Exchange notes that it is amending Rule 4.13 to include the Nasdaq 100 Micro Index Options within the Rule to conform to the amendments proposed herein.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.³³ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³⁴ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and

³² See ISE Rules, Options 4A, Section 6 (Position Limits) and Section 10 (Exercise Limits).

³³ 15 U.S.C. 78f(b).

³⁴ 15 U.S.C. 78f(b)(5).

practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³⁵ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change will further the Exchange’s goal of introducing new and innovative products to the marketplace. Specifically, the Exchange believes that XND options would provide additional opportunities for market participants to trade and hedge exposure to the Nasdaq-100 Index as it does today on ISE and Phlx. The proposed XND options product is identical to XND options on ISE and Phlx. Additionally, the proposed XND options product is similar to NDX options that are currently permitted to be listed and traded on the Exchange with two important differences: (1) XND options will be based on 1/100 the value of the Nasdaq-100 Index, and (2) XND options will be P.M.-settled (in addition to being A.M.-settled). These differences are based on the Exchanges experience listing NDX options and are designed to attract additional participation from retail and other investors.

The Exchange believes that the proposed contract specifications will be attractive to market participants and will remove impediments to and perfect the mechanism of a free and open market and a national market system. The nonstandard expirations would expand the ability of investors to hedge risks against market movements stemming from economic releases or market events that occur during the month and at the end of the month. Accordingly, the Exchange believes that weekly expirations and EOMs should create greater trading and hedging opportunities and flexibility, and provide customers with the ability to tailor their investment objectives more closely.

The Exchange believes that a micro index option would allow additional participation from investors. Specifically, the Exchange believes that basing the contract on a micro value of the Nasdaq-100 Index will encourage

³⁵ *Id.*

additional participation by retail and other investors due to the reduced capital outlay needed to trade these options.

XND options will be subject to the same rules that presently govern the trading of index options based on the Nasdaq-100 Index, including sales practice rules, margin requirements, trading rules, and position and exercise limits. The Exchange therefore believes that the rules applicable to trading in XND options are consistent with the protection of investors and the public interest. Furthermore, the Exchange represents that it has sufficient systems capacity and adequate surveillance procedures to handle trading in XND options.

With respect to the Exchange's proposal to provide that minimum increments for bids and offers for XND options be the same as those for QQQ, regardless of the value at which the option series is quoted, may promote competition and benefit investors. This proposal aligns the minimum increments for XND options with those for QQQ options in order to allow market participants to quote in minimum increments of \$0.01 is consistent with the Act because allowing participants to quote in smaller increments may provide the opportunity for reduced spreads, thereby lowering costs to investors. In addition, because both XND and QQQ are based on the Nasdaq-100 Index it would be reasonable for the minimum increments of bids and offers to be the same for both types of options.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. XND options would be available for trading to all market participants. The proposed rule change will facilitate the listing and trading of a new option product that will enhance competition among market participants, to the benefit of investors and the marketplace. The listing of XND will enhance competition by providing investors with an additional investment vehicle, in a fully-electronic trading environment, through which investors can gain and hedge exposure to the Nasdaq-100 Index. Furthermore, this product could offer a competitive alternative to other existing investment products that seek to allow investors to gain broad market exposure. Finally, two other exchanges currently list the same product for trading in accordance with substantially similar rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³⁶ and Rule 19b-4(f)(6) thereunder.³⁷ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act³⁸ and Rule 19b-4(f)(6)(iii) thereunder.³⁹

A proposed rule change filed under Rule 19b-4(f)(6)⁴⁰ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),⁴¹ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. As discussed above, the Exchange states that this proposed rule change is substantially similar to a proposal submitted by Phlx⁴² that was previously approved by the Commission, as well as a proposal submitted by ISE⁴³ that was subject to

Commission review. The Exchange also stated that the two other exchanges currently list the same product for trading in accordance with substantially similar rules. The Exchange believes that the waiver of the operative delay will protect investors by allowing the Exchange to implement the proposal expeditiously, and it will promote competition by providing an additional venue upon which to trade this product. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will permit the Exchange to remain competitive with other exchanges and provide immediate choice to market participants to readily direct order flow to competing venues who offer similar functionality. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.⁴⁴

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)⁴⁵ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CBOE-2024-043 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.

Immediate Effectiveness of Proposed Rule Change To Permit the Listing and Trading of XND Options).

⁴⁴ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁴⁵ 15 U.S.C. 78s(b)(2)(B).

³⁶ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁷ 17 CFR 240.19b-4(f)(6).

³⁸ 15 U.S.C. 78s(b)(3)(A).

³⁹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

⁴⁰ 17 CFR 240.19b-4(f)(6).

⁴¹ 17 CFR 240.19b-4(f)(6)(iii).

⁴² See Securities Exchange Act Release No. 98451 (September 20, 2023), 88 FR 66088 (September 26, 2023) (SR-Phlx-2023-07) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Make Permanent Certain P.M.-Settled Pilots).

⁴³ See Securities Exchange Act Release No. 98886 (November 8, 2023), 88 FR 78417 (November 15, 2023) (SR-ISE-2023-24) (Notice of Filing and

All submissions should refer to file number SR-CBOE-2024-043. 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-CBOE-2024-043 and should be submitted on or before October 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁶

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024-22026 Filed 9-25-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101118; File No. SR-MSRB-2024-01]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend MSRB Rule G-14 To Shorten the Timeframe for Reporting Trades in Municipal Securities to the MSRB

September 20, 2024.

I. Introduction

On January 12, 2024, the Municipal Securities Rulemaking Board ("MSRB") filed with the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to (1) amend MSRB Rule G-14 ("Rule G-14"), on reports of sales or purchases, to (i) shorten the amount of time within which brokers, dealers, and municipal securities dealers (collectively, "dealers," and each individually, a "dealer") must report most transactions to the MSRB; and (ii) require dealers to report certain transactions with a new trade indicator, and make certain clarifying amendments, and (2) make conforming amendments to MSRB Rule G-12, on uniform practice ("Rule G-12"), and the MSRB's Real-Time Transaction Reporting System ("RTRS") Information Facility ("IF-1") to reflect the shortened reporting timeframe (the "original proposed rule change"). The original proposed rule change was published for comment in the **Federal Register** on January 26, 2024.³ The Commission received comments in response to the original proposed rule change.⁴ On April 22, 2024, the

Commission issued an order instituting proceedings ("OIP") under Section 19(b)(2)(B) of the Act⁵ to determine whether to approve or disapprove the proposed rule change.⁶ The Commission received comments in response to the OIP.⁷ On July 18, 2024, the Commission, pursuant to Section 19(b)(2) of the Act,⁸ designated September 20, 2024, as the date by which the Commission shall either approve or disapprove the original proposed rule change.⁹ Also on July 18, 2024, the MSRB filed a comment letter¹⁰ and an amendment to the original proposal in response to certain comments on the original proposed rule change ("Amendment No. 1"; the original proposed rule change, as modified by Amendment No. 1, the "proposed rule change"). On July 25, 2024, the Commission published notice

and CEO, Securities Industry and Financial Markets Association ("SIFMA") dated Feb. 15, 2024 ("SIFMA Letter"); Howard Meyerson, Managing Director, Financial Information Forum ("FIF") dated Feb. 15, 2024 ("FIF I Letter"); Gregory Babyak, Global Head of Regulatory Affairs, Bloomberg L.P. dated Feb. 16, 2024 ("Bloomberg Letter"); Melissa P. Hoots, CEO/COO, Falcon Square Capital, LLC ("Falcon Square Capital") dated Feb. 16, 2024 ("Falcon Square Capital Letter"); Matt Dalton, Chief Executive Officer, Belle Haven Investments, LP ("Belle Haven") dated Feb. 16, 2024 ("Belle Haven Letter"); and Christopher A. Iacovella, President & Chief Executive Officer, American Securities Association ("ASA") dated Feb. 16, 2024 ("ASA Letter"). After the close of the comment period, one commenter submitted a supplemental letter. See letter to Secretary, Commission, from Howard Meyerson, FIF dated Feb. 26, 2024 ("FIF II Letter"). These comment letters are available at <https://www.sec.gov/comments/sr-msrb-2024-01/srmsrb202401.htm>.

⁵ 15 U.S.C. 78s(b)(2)(B).

⁶ See Exchange Act Release No. 100003 (Apr. 22, 2024), 89 FR 32486 (Apr. 26, 2024).

⁷ See Letters to Secretary, Commission, from David C. Jaderlund dated Apr. 23, 2024 ("Jaderlund OIP Letter"); Ronald P. Bernardi, President and CEO, Bernardi Securities, Inc. dated May 14, 2024 ("Bernardi Securities OIP Letter"); Frank Fairman, Managing Director, Piper Sandler & Co. dated May 17, 2024 ("Piper Sandler OIP Letter"); Christopher A. Iacovella, ASA dated May 17, 2024 ("ASA OIP Letter"); Michael Decker, BDA dated May 17, 2024 ("BDA OIP Letter"); Mark D. Griffin, Senior Vice President and Risk Control Manager, FHN Financial dated May 17, 2024 ("FHN Financial OIP Letter"); Howard Meyerson, FIF dated May 17, 2024 ("FIF OIP Letter"); Richard G. Wallace, Senior Vice President and Associate General Counsel, LPL Financial LLC ("LPL") dated May 17, 2024 ("LPL OIP Letter"); Lisa Gayle Melnyk dated May 17, 2024 ("Melnik OIP Letter"); Kenneth E. Bentsen, Jr., SIFMA dated May 17, 2024 ("SIFMA OIP Letter"). These comment letters are available at <https://www.sec.gov/comments/sr-msrb-2024-01/srmsrb202401.htm>.

⁸ 15 U.S.C. 78s(b)(2).

⁹ See Exchange Act Release No. 100557 (July 18, 2024), 89 FR 59951 (July 24, 2024).

¹⁰ See Letter to Secretary, Commission, from Ernesto A. Lanza, Chief Regulatory and Policy Officer, MSRB, dated July 18, 2024, available at <https://www.sec.gov/comments/sr-msrb-2024-01/srmsrb202401.htm> ("MSRB Letter").

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Exchange Act Release No. 99402 (Jan. 19, 2024), 89 FR 5384 (Jan. 26, 2024) ("Notice").

⁴ See Letters to Secretary, Commission, from Michael Noto, FINRA Registered Representative dated Jan. 31, 2024 ("Noto Letter"); J. Ben Watkins, Director, Division of Bond Finance, State of Florida dated Feb. 13, 2024 ("State of Florida Letter"); Matthew Kamler, President, Sanderlin Securities LLC dated Feb. 14, 2024 ("Sanderlin Securities Letter"); J.D. Colwell dated Feb. 15, 2024 ("Colwell Letter"); Gerard O'Reilly, Co-Chief Executive Officer and Co-Chief Investment Officer and David A. Plecha, Global Head of Fixed Income, Dimensional Fund Advisors LP dated Feb. 15, 2024 ("Dimensional Fund Advisors Letter"); Michael Decker, Senior Vice President, Bond Dealers of America ("BDA") dated Feb. 15, 2024 ("BDA Letter"); Sarah A. Bessin, Deputy General Counsel and Kevin Ercoline, Assistant General Counsel, Investment Company Institute dated Feb. 15, 2024 ("ICI Letter"); Kenneth E. Bentsen, Jr., President

⁴⁶ 17 CFR 200.30-3(a)(12).

of Amendment No. 1,¹¹ and the Commission received comment letters in response.¹² This order approves the proposed rule change.

II. Description of the Proposed Rule Change

As described more fully in the Notice and Amendment No. 1, the MSRB is proposing amendments to Rule G–14, Reports of Sales or Purchases, and conforming technical changes to Rule G–12(f)(i) and IF–1.

The MSRB believes that the proposed rule change would remove impediments to a free and open market in municipal securities by making publicly available more timely information about the market and the prices at which municipal securities transactions are executed, which is central to fairly priced municipal securities and a dealer's ability to make informed quotations.¹³ Additionally, the MSRB is of the view that the new intra-day exceptions balance potential burdens for dealers with limited trading activity and address potential burdens faced by dealers engaged in complex transactions, including voice/electronically negotiated transactions involving a manual post-transaction component.¹⁴

As the proposed rule change was developed in close coordination with the Financial Industry Regulatory Authority (“FINRA”),¹⁵ the MSRB is of the view that the proposed rule change reduces the risk of potential confusion and may reduce compliance burdens resulting from inconsistent obligations and standards for different classes of securities.¹⁶ According to the MSRB, a shortened trade reporting time would promote regulatory consistency,

reducing potential compliance violations caused by market participants' imperfect application of differing standards when executing and reporting various types of transactions in fixed income securities.¹⁷

A. New Baseline Reporting Requirement: One Minute After the Time of Trade

The proposed amendments to Rule G–14 RTRS Procedures Section (a)(ii) generally would provide that transactions effected with a Time of Trade during the hours of an RTRS Business Day¹⁸ must be reported to an RTRS Portal¹⁹ “as soon as practicable, but no later than one minute” after the Time of Trade, subject to several existing reporting exceptions, which would be retained in the amended rule,²⁰ and two new intra-day reporting exceptions relating to dealers with limited trading activity and trades with a manual component that would be added by the proposed rule change.²¹ Except for those trades that would qualify for a reporting exception, all trades currently required to be reported within 15 minutes after the Time of Trade would, under the proposed rule change, be required to be reported no later than one minute after the Time of Trade.

i. New Requirement To Report Trades “as Soon as Practicable”

Section (a)(ii) of the proposed amendment to Rule G–14 RTRS Procedures adds a new requirement that, absent an exception, trades must be reported as soon as practicable (but no later than one minute after the Time of Trade).²² This “as soon as practicable” requirement would also apply to trades subject to longer trade reporting deadlines under the two new exceptions for dealers with limited trading activity pursuant to Rule G–14 RTRS Procedures Section (a)(ii)(C)(1) and Supplementary Material .01, or trades with a manual component pursuant to Rule G–14 RTRS Procedures Section (a)(ii)(C)(2) and

Supplementary Material .02.²³ Although Rule G–14 RTRS Procedures do not currently explicitly prohibit a dealer from waiting until the existing 15-minute deadline to report a trade notwithstanding the fact that the dealer could reasonably have reported such trade more rapidly, the MSRB notes that under the proposed rule change a dealer could not simply await the deadline to report a trade if it were practicable to report such trade more rapidly.²⁴

As provided in more detail in the Notice, proposed Supplementary Material .03 would provide guidance relating to policies and procedures for complying with the “as soon as practicable” reporting requirement.²⁵ The MSRB noted that dealers must not purposely withhold trade reports, for example, by programming their systems to delay reporting until the last permissible minute or by otherwise delaying reports to a time just before the deadline if it would have been practicable to report such trades more rapidly.²⁶ For trades with a manual component, and consistent with Supplementary Material .03(b) of FINRA Rule 6730, the MSRB recognized that the trade reporting process may not be completed as quickly as, for example, where an automated trade reporting system is used.²⁷ The MSRB explained that it expected that the regulatory authorities that examine dealers and enforce compliance with this requirement would take into consideration the manual nature of the dealer's trade reporting process in determining whether the dealer's policies and procedures are reasonably designed to report the trade “as soon as practicable” after execution.²⁸

ii. Time of Trade Discussion

The “Time of Trade” is defined as the time at which a contract is formed for a sale or purchase of municipal securities at a set quantity and set price.²⁹ For transaction reporting purposes, the MSRB stated that the Time of Trade is the same as the time that a trade is “executed” and, generally, is consistent with the “time of

¹¹ See Exchange Act Release No. 100589 (July 24, 2024), 89 FR 61516 (July 31, 2024) (“Amendment No. 1”).

¹² See Letters to Secretary, Commission, from Guerras Global International, University of Providence dated July 29, 2024 (“Guerras Global Amendment No. 1 Letter”); Kenneth E. Bentsen, Jr., SIFMA dated Aug. 21, 2024 (“SIFMA Amendment No. 1 Letter”); Christopher A. Iacovella, ASA dated Aug. 21, 2024 (“ASA Amendment No. 1 Letter”); Matt Dalton, Belle Haven dated Aug. 21, 2024 (“Belle Haven Amendment No. 1 Letter”); Melissa P. Hoots, Falcon Square dated Aug. 21, 2024 (“Falcon Square Capital Amendment No. 1 Letter”); Michael Decker, BDA dated Aug. 21, 2024 (“BDA Amendment No. 1 Letter”). These comment letters are available at <https://www.sec.gov/comments/sr-msrb-2024-01/srmsrb202401.htm>.

¹³ See MSRB Letter at 5.

¹⁴ *Id.*

¹⁵ See Securities Exchange Act Release No. 99404 (Jan. 19, 2024), 89 FR 5034 (Jan. 24, 2024) (“FINRA Notice”), as partially amended by Securities Exchange Act Release No. 100594 (July 25, 2024), 89 FR 61514 (July 31, 2024) (“Partial Amendment No. 1,” and together with the FINRA Notice, the “FINRA proposed rule change”).

¹⁶ See MSRB Letter at 4.

¹⁷ *Id.*

¹⁸ Rule G–14 RTRS Procedures Section (d)(ii) defines “RTRS Business Day” as 7:30 a.m. to 6:30 p.m., Eastern Time, Monday through Friday, unless otherwise announced by the MSRB.

¹⁹ See Notice, 89 at 5385 n.13 (discussing the various portals).

²⁰ *Id.* at 5385 n.14 (describing the existing exceptions).

²¹ The two new intra-day reporting exceptions, consisting of trades by dealers with limited trading activity and trades with a manual component, would be designated as Rule G–14 RTRS Procedures Sections (a)(ii)(C)(1) and (2), respectively. See Notice, 89 FR at 5385 n.15; Amendment No. 1.

²² See Notice, 89 FR at 5386.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.* Where a dealer has reasonably designed policies, procedures and systems in place, the dealer generally would not be viewed as violating the “as soon as practicable” requirement because of delays in trade reporting due to extrinsic factors that are not reasonably predictable and where the dealer does not intend to delay the reporting of the trade (for example, due to a systems outage).

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ See current Rule G–14 RTRS Procedures Section (d)(iii).

execution” for recordkeeping purposes.³⁰

iii. Valid Contract Discussion

In general, to form a valid contract, there must be at least an offer and acceptance of that offer. As a result, the MSRB noted that dealers should consider the point in time at which an offer to buy or sell municipal securities was met with an acceptance of that offer. This “meeting of the minds,”³¹ cannot occur before the final material terms, such as the exact security, price and quantity, have been agreed to and such terms are known by the parties to the transaction.³² The MSRB further explained that dealers should be clear in their communications regarding the final material terms of the trade and how such terms would be conveyed between the parties³³ to ensure that such a valid trade contract has been formed.³⁴

iv. Exceptions to the Baseline Reporting Requirement

Proposed amendments to Rule G–14 RTRS Procedures Section (a)(ii) add two new exceptions to the proposed one-minute reporting requirement: (a) New Section (C)(1) provides an exception for a dealer with “limited trading activity,” and (b) New Section (C)(2) provides an exception for a dealer reporting a “trade with a manual component.”³⁵

a. Exception for Dealers With Limited Trading Activity

Proposed new Section (a)(ii)(C)(1) would except a dealer with “limited trading activity” from the one-minute reporting requirement and would

instead be required to report its trades as soon as practicable, but no later than 15 minutes after the Time of Trade for so long as the dealer remains qualified for the limited trading activity exception, as further specified in new Supplementary Material .01.³⁶ Proposed Section (d)(xi) of Rule G–14 RTRS Procedures would define a dealer with limited trading activity as a dealer that, during at least one of the prior two consecutive calendar years, reported to an RTRS Portal fewer than 2,500 purchase or sale transactions with customers or other dealers,³⁷ excluding transactions exempted under Rule G–14(b)(v) and transactions specified in Rule G–14 RTRS Procedures Sections (a)(ii)(A) and (B). A dealer relying on this exception to report trades within the 15-minute timeframe, rather than the new standard one-minute timeframe, would have to confirm that it meets the criteria for a dealer with limited trading activity for each year during which it continues to rely on the exception (e.g., the dealer could confirm its eligibility based on its internal trade records and by checking MSRB compliance tools which would indicate a dealer’s transaction volume for a given year).³⁸

b. Exception for Trades With a Manual Component

Rule G–14 RTRS Procedures Section (a)(ii)(C)(2) would except a “trade with a manual component” as defined in new Section (d)(xii) of Rule G–14 RTRS Procedures from the one-minute reporting requirement. The MSRB noted that dealers with such trades would be required to report such trades as soon as practicable and within the time periods

specified in new Supplementary Material .02, unless another exception from the one-minute reporting requirement applies under proposed Rule G–14 RTRS Procedures Sections (a)(ii)(A) and (B) (i.e., transactions having an end-of-trade-day or post-trade-day reporting exception) or (a)(ii)(C)(1) (i.e., transactions by dealers with limited trading activity).³⁹ Section (d)(xii) of Rule G–14 RTRS Procedures would define a “trade with a manual component” as a transaction that is manually executed or where the dealer must manually enter any of the trade details or information necessary for reporting the trade directly into an RTRS Portal (for example, by manually entering trade data into the RTRS Web Portal) or into a system that facilitates trade reporting (for example, by transmitting the information manually entered into a dealer’s in-house or third-party system) to an RTRS Portal. As described below and more fully in the Notice, a dealer reporting to the MSRB a trade meeting the definition for a “trade with a manual component” would be required to append a new trade indicator so that the MSRB can identify manual trades.⁴⁰

As explained by the MSRB, this “manual” exception would apply narrowly, and would normally encompass any human participation, approval or other intervention necessary to complete the initial execution and reporting of trade information after execution, regardless of whether undertaken by electronic means (e.g., keyboard entry), physical signature or other physical action. To qualify as a trade with a manual component, the manual aspect(s) of the trade generally would have to occur after the relevant Time of Trade (i.e., the time at which a contract is formed for the transaction).⁴¹ As further explained by the MSRB, any manual aspects that precede the time of trade (e.g., phone calls to locate bonds to be sold to a customer before the dealer agrees to sell such bonds to a purchasing customer) would normally not be relevant for purposes of the exception unless they have a direct impact on the activities that must be

³⁰ See Notice, 89 FR at 5386–87 (discussing time of execution and note 22 for additional guidance on the time of execution); MSRB Letter at 13 (MSRB further explaining that the Time of Trade is the time at which a meeting of the minds has occurred, for example, where parties have already reached agreement regarding the terms and elements of execution and at what point a contract is formed for the transaction).

³¹ See generally FINRA Regulatory Notice 16–30 (Trade Reporting and Compliance Engine (TRACE): FINRA Reminds Firms of their Obligation to Report Accurately the Time of Execution for Transactions in TRACE-eligible Securities) (Aug. 2016); MSRB Notice 2016–19 (MSRB Provides Guidance on MSRB Rule G–14, on Reports of Sales or Purchases of Municipal Securities (Aug. 9, 2016) (the “2016 RTRS FAQs”) at questions 1 and 2.

³² See generally MSRB Notice 2004–18 (Notice Requesting Comment on Draft Amendments to Rule G–34 to Facilitate Real-Time Transaction Reporting and Explaining Time of Trade for Reporting New Issue Trades) (June 18, 2004); 2016 RTRS FAQs at question 1.

³³ See Notice, 89 FR at 5386 n.26.

³⁴ *Id.* at 5387 (discussing the particulars for when transactions have been executed, confirmed, and reported).

³⁵ *Id.* (explaining how these exceptions have a narrowly tailored purpose).

³⁶ The MSRB noted that transactions effected by such a dealer with a Time of Trade outside the hours of an RTRS Business Day would be permitted to be reported no later than 15 minutes after the beginning of the next RTRS Business Day pursuant to Rule G–14 RTRS Procedures Section (a)(iii). The MSRB also noted that, as is the case today, transactions for which an end-of-trade-day or post-trade-day reporting exception is available under redesignated Sections (A) and (B) would continue to have that exception available. See Notice, 89 FR at 5387 n.29.

³⁷ The original proposed rule change established a threshold of 1,800 trades. See Notice, 89 FR at 5387. The MSRB recalculated the appropriate threshold for the definition of “dealer with limited trading activity” to take into account both sell-side and buy-side inter-dealer trade reports together with reports of dealer trades with customers, regardless of whether the dealer bought or sold in the customer transaction. See Amendment No. 1; MSRB Letter at 22 n.81. The MSRB stated that there is no material impact to the economic analysis contained in the original proposed rule change as a result of the increased threshold. See MSRB Letter at 23.

³⁸ See Notice, 89 FR at 5387–88 (MSRB using a hypothetical to illustrate variations in dealer eligibility for the limited trading exception).

³⁹ As explained by the MSRB, transactions effected with a Time of Trade outside the hours of an RTRS Business Day would be permitted to be reported no later than 15 minutes after the beginning of the next RTRS Business Day pursuant to Rule G–14 RTRS Procedures Section (a)(iii). See Notice, 89 FR at 5388 n.38.

⁴⁰ Such new indicator would be required for any trade with a manual component, whether the dealer reports such trade within the new one-minute timeframe or the dealer seeks to take advantage of the longer timeframes permitted for trades with a manual component. See Notice, 89 FR at 5388 n.39.

⁴¹ *Id.* at 5388.

undertaken post-execution to enter information necessary to report the trade.⁴²

The MSRB provided the following non-exhaustive list of situations in which trades would be considered to have a manual component:

- where a dealer executes a trade by manual or hybrid means, such as voice or negotiated trading by telephone, email, or through a chat/messaging function, and subsequently must manually enter into a system that facilitates trade reporting all or some of the information required to book the trade and report it to RTRS;⁴³
- where a dealer executes a trade (typically a larger-sized trade) that requires additional steps to negotiate and confirm details of the trade with a client and manually enters the trade into risk and reporting systems;⁴⁴
- where a dually-registered broker-dealer/investment adviser executes a block transaction that requires allocations of portions of the block trade to the individual accounts of the firm's advisory clients that must be manually inputted in connection with a trade;⁴⁵
- where an electronically or manually executed trade is subject to manual review by a second reviewer for risk management (e.g., transactions above a certain dollar or par amount or other transactions meriting heightened risk review) and, as part of or following the review, the trade must be manually approved, amended or released before the trade is reported to RTRS;⁴⁶
- where a dealer's trade execution processes may entail further diligence following the Time of Trade involving a manual step (e.g., manually checking another market to confirm that a better price is not available to the customer);⁴⁷
- where a dealer trades a municipal security, whether for the first time or under other circumstances where the security master information may not already be populated (e.g., information has been removed or archived due to a long lapse in trading the security), and

⁴² The MSRB provided various scenarios to illustrate application of the manual exception would apply. *See generally id.* at 5389 n.40. The MSRB further clarified that the exception is intended to apply only to the trade execution and reporting portions of the workflow. *See MSRB Letter* at 13.

⁴³ *See Notice*, 89 FR at 5389.

⁴⁴ *See Notice*, 89 FR at 5389.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ The MSRB noted that dealers experiencing significant levels of post-Time of Trade price adjustments due to such post-trade best execution processes should consider whether these processes are well suited to the dealer's obligations under MSRB Rule G-18 and whether the dealer is appropriately evaluating when a contract has in fact been formed with its customer. *Id.* at 5389 n.41.

additional manual steps are necessary to set up the security and populate the associated indicative data in the dealer's systems prior to executing and reporting the trade;⁴⁸

- where a dealer receives a large order or a trade list resulting in a portfolio of trades with potentially numerous unique securities involving rapid execution and frequent communications on multiple transactions with multiple counterparties, and the dealer must then book and report those transactions manually, one by one;⁴⁹
- where a broker's broker engages in mediated transactions that involve multiple transactions with multiple counterparties;⁵⁰ and
- where a dealer reports a trade manually through the RTRS Web Portal.⁵¹

The MSRB noted that appropriateness of treating any step in the trade execution and reporting process as being manual must be assessed in light of the anti-circumvention provision included in the proposed rule change with regard to the delay in execution or insertion of manual tasks for the purpose of meeting this new exception.⁵²

New Supplementary Material .02(a) would require all trades with a manual component to be reported as soon as practicable and would specify that in no event may a dealer purposely delay the execution of an order, introduce any manual steps following the Time of Trade, or otherwise modify any steps prior to executing or reporting a trade for the purpose of utilizing the exception for manual trades.⁵³

New Supplementary Material .03 would require that dealers adopt policies and procedures for complying with the as soon as practicable reporting requirement, including by implementing systems that commence the trade reporting process without delay upon execution and provides for additional guidance for regulatory authorities that enforce and examine

⁴⁸ *Id.* at 5389.

⁴⁹ The MSRB explained that in instances where a dealer trades a basket of securities at a single price for the full basket, rather than individual prices for each security based on its then-current market price, such price likely would be away from the market, requiring inclusion of the "away from market" special condition indicator and qualifying for an end-of-trade-day reporting exception under proposed Rule G-14 RTRS Procedures Section (a)(ii)(A)(3). *See Notice*, 89 FR at 5389 n.42.

⁵⁰ *Id.* at 5389.

⁵¹ *Id.*

⁵² *Id.* at 5390 (discussing the prohibition on purposeful insertion of manual steps in trade reporting process).

⁵³ *Id.*

dealers for compliance with this requirement to take into consideration the manual nature of the dealer's trade reporting process.⁵⁴

The MSRB also noted that dealers should consider the types of transactions in which they regularly engage and whether they can reasonably reduce the time between a transaction's Time of Trade and its reporting, and more generally should make a good faith effort to report their trades as soon as practicable.⁵⁵ The MSRB currently collects and analyzes data regarding dealers' historic reporting of transactions to RTRS under various scenarios and such data will continue to be available to the regulators for analysis under the proposed one-minute standard. Subject to Commission approval of the proposed rule change, the MSRB explained that it would be reviewing the use of the manual exception and would share with the examining authorities any analyses resulting from such reviews.⁵⁶

1. Phase-In Period for Trades With a Manual Component

New Supplementary Material .02(b) would subject trades with a manual component to a phase-in period for timely reporting over three years ("phase-in period"). During the first calendar year of effectiveness of the exception, trades meeting this definition would be required to be reported as soon as practicable, but no later than 15 minutes after the Time of Trade.⁵⁷ For the second and third calendar years from effectiveness of the exception, such trades would be required to be reported as soon as practicable, but no later than 10 minutes after the Time of Trade.⁵⁸

Following the conclusion of the third calendar year and thereafter, such trades

⁵⁴ For trades with a manual component, the MSRB explained that it recognized that the trade reporting process may not be completed as quickly as, for example, where an automated trade reporting system is used. The MSRB further explained that in these cases, the MSRB expects that the regulatory authorities that examine dealers and enforce compliance with this requirement would take into consideration the manual nature of the dealer's trade reporting process in determining whether the dealer's policies and procedures are reasonably designed to report the trade "as soon as practicable" after execution. *See id.* at 5388.

⁵⁵ *Id.* at 5389.

⁵⁶ *Id.* at 5390.

⁵⁷ *Id.* at 5389; Amendment No. 1, Supplementary Material .02(b)(i).

⁵⁸ Under the original proposed rule change, trades with a manual component would have been required to be reported as soon as practicable, but no later than five minutes after the Time of Trades after the second calendar year from effectiveness and thereafter. *See Notice*, 89 FR at 5390; Amendment No. 1, Supplementary Material .02(b)(ii).

would be required to be reported as soon as practicable, but no later than five minutes after the Time of Trade.⁵⁹ The MSRB stated that dealers should remember that the “as soon as practicable” reporting obligation may, depending on the facts and circumstances, require quicker reporting than the applicable outer reporting obligation during and after the phase-in period.

2. Prohibition on Purposeful Insertion of Manual Steps in Trade Reporting Process

New Supplementary Material .02(a) would specifically prohibit dealers from purposely delaying the execution of an order, introducing any manual steps following the Time of Trade, or otherwise purposefully modifying any steps to execute or report a trade to utilize the exception for manual trades. The MSRB notes that this requirement would not prohibit reasonable manual steps that are taken for legitimate purposes and would not apply to any steps that are taken prior to the time of trade that do not have the effect of delaying the subsequent reporting of such trade.⁶⁰

3. Manual Trade Indicator

Proposed amendments to Rule G–14 RTRS Procedures Section (b)(iv) would require the report of a trade meeting the MSRB’s definition for a “trade with a manual component,” as defined in proposed Section (d)(xii) of Rule G–14 RTRS Procedures,⁶¹ to append a new trade indicator⁶² to such a trade report. The MSRB noted that this indicator would be mandatory for every trade that meets the standard to append the indicator,⁶³ regardless of whether the trade is actually reported within one minute after the Time of Trade, is

reported within the applicable timeframe under the manual trade exception or is otherwise subject to another reporting exception.

v. Pattern or Practice of Late Trade Reporting

Current Rule G–14 RTRS Procedures Section (a)(iv) requires that transaction data that is not submitted in a timely and accurate manner must be submitted or corrected as soon as possible—even when a dealer is late in reporting a trade, the dealer remains obligated to report such trade as soon as possible. The proposed rule change further provides that any transaction that is not reported within the applicable time period shall be designated as “late.”⁶⁴ The MSRB stated that a pattern or practice of late reporting without exceptional circumstances or reasonable justification may be considered a violation of Rule G–14.⁶⁵ The MSRB further noted that the determination of whether exceptional circumstances or reasonable justifications exist for late trade reporting is dependent on the particular facts and circumstances and whether such circumstances are addressed in the dealer’s systems and procedures.⁶⁶ The MSRB explained that it expected that the regulatory authorities that examine dealers and enforce compliance with the reporting timeframes established under Rule G–14 RTRS Procedures would focus their examination for and enforcement of the rule’s timing requirements on the consistency of timely reporting and the existence of effective controls to limit late reporting to exceptional circumstances or where reasonable justifications exist for a late trade report, rather than on individual late trade report outliers.⁶⁷ Notwithstanding such expectation, where facts and circumstances indicate that an individual late report was intentional or otherwise egregious, or could reasonably be viewed as potentially giving rise to an associated fair practice, fair pricing, best execution or other material regulatory concern under MSRB or Commission rules with respect to that or a related transaction, the MSRB noted that the regulatory authorities could reasonably determine to take action with respect to such late

trade in the examination or enforcement context.⁶⁸

vi. Compliance Tools

The MSRB explained that it would continue to provide various compliance tools to assist dealers with compliance and for examining authorities to monitor for compliance.⁶⁹

vii. Other Proposed Amendments

a. Technical Amendments

Technical amendments to Rule G–14 RTRS Procedures Section (a)(ii) regroup and renumber its current Sections (A) through (C) to new Sections (A)(1) through (A)(3), renumber current Sections (D) and (E) to new Sections (B)(1) and B(2), and correct a cross-reference in Section (b)(iv) to certain of these Sections to be consistent with such renumbering.⁷⁰ In addition, a technical amendment to Rule G–14 RTRS Procedures Section (a)(ii) changes the word “of” to “after” and omits the word “within” in the phrase “within 15 minutes of Time of Trade” for clarity and consistency of usage throughout the Rule G–14 RTRS Procedures as amended.⁷¹

b. Clarifying Amendments—Special Condition Indicators and Trades on an Invalid RTTM Trade Date

Rule G–14 RTRS Procedures Section (b)(iv) currently sets forth information regarding certain existing special condition indicators while also referencing the existence of other special condition indicators in Section 4.3.2 of the Specifications for Real-Time Reporting of Municipal Securities Transactions. The MSRB stated that the proposed clarifying amendments to Section (b)(iv) of Rule G–14 RTRS Procedures would incorporate into the language thereof reference to all applicable special condition indicators, including the new trade with a manual component indicator and existing special condition indicators previously adopted by the MSRB but that are currently only documented explicitly in the Specifications for Real-Time Reporting of Municipal Securities Transactions.⁷² Other than the addition of the new trade with a manual component indicator, the MSRB noted that the proposed clarifying amendments to this provision would not make any changes to the types or usage of existing special condition

⁵⁹ See Notice, 89 FR at 5387. The MSRB explained that it would be monitoring the implementation of the proposed rule change and would analyze trade data to determine, among other things, whether the eventual five-minute trade reporting timeframe continues to be feasible and appropriate in light of the empirical data collected through the earlier phases of implementation. See Amendment No. 1. The MSRB further explained that any further reduction in reporting timeframe, or elimination of the manual trade exception, could not be possible without additional formal rulemaking by the MSRB that would be filed with the Commission. See Amendment No. 1.

⁶⁰ See Notice, 89 FR at 5390.

⁶¹ See generally *id.* at 5388–90.

⁶² *Id.* at 5391 n.51 (discussing how the manual trade indicator would be used for regulatory purposes).

⁶³ Current Rule G–14 RTRS Procedures Section (a)(iv) requires that transaction data that is not submitted in a timely and accurate manner must be submitted or corrected as soon as possible. The manual trade indicator is not intended to be used to reflect the manual nature of any correction to a prior trade report. *Id.* at 5390 n.50.

⁶⁴ See generally *id.* at 5391 n.52 (MSRB explaining that late trade designations are currently, and would continue to be, available to regulators and, through the MSRB compliance tool described below in the Notice under “Purpose—Proposed Rule Change—Compliance Tools,” to the dealer submitting the late trade).

⁶⁵ *Id.* at 5391.

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.* at 5392.

⁷¹ *Id.*

⁷² See generally *id.* at 5392 n.55.

indicators.⁷³ Rule G–14 RTRS Procedures Section (a)(iii) would be amended to reflect that, in addition to trades effected outside the hours of the RTRS Business Day, inter-dealer trades may be executed on certain holidays (other than those recognized as non-RTRS Business Days) that are not valid RTTM trade dates (“invalid RTTM trade date”), and in either case such trades are to be reported no later than within 15 minutes after the beginning of the next RTRS Business Day. Such invalid RTTM trade date transactions are already subject to this same next RTRS Business Day reporting requirement.⁷⁴ The MSRB believes that a proposed clarifying amendment to this provision would not make any changes to the circumstances or timing of reporting of such trades.⁷⁵

c. Proposed Conforming Amendments to Rule G–12 and RTRS Information Facility

Proposed amendments to Rule G–12, on uniform practice, would make conforming changes to Section (f)(i) thereof to require that each transaction effected during the RTRS Business Day shall be submitted for comparison as soon as practicable, but no later than one minute after the Time of Trade unless an exception applies. The proposed rule change would also modify the IF–1 to clarify lateness checking against the applicable reporting deadline(s) provided for in proposed amendments to Rule G–14 RTRS Procedures, as opposed to the current 15-minute requirement.⁷⁶

III. Summary of Comments Received and the MSRB’s Response

As noted previously, the Commission received fourteen (14) comments letters in response to the Notice, ten (10) letters in response to the OIP, and six (6) letters in response to Amendment No. 1.⁷⁷ The

MSRB responded to the comment letters received on the Notice and OIP in the MSRB Letter.⁷⁸ The MSRB reiterated that it continues to believe that the proposed rule change would promote just and equitable principles of trade because it would further reduce information asymmetry between market professionals (such as dealers and institutional investors) and retail investors by ensuring progressively increased access to more timely information about executed municipal securities transactions for all investors.⁷⁹ Additionally, the MSRB explained that the proposed rule change would foster cooperation and coordination with persons engaged in regulating and processing information, facilitating a consistent standard for trade reporting across many fixed income products, including municipal securities.⁸⁰ The MSRB further noted that the proposed rule change would remove impediments to a free and open market in municipal securities by making publicly available more timely information about the market and the prices at which municipal securities transactions are executed and promote investor protection and the public interest through increased market transparency.⁸¹ Commenters generally supported the MSRB’s goal of facilitating equal access to information and market transparency.⁸²

A. One-Minute Reporting

i. Benefit to Municipal Securities Market

Some commenters expressed concern that the scope of the proposed rule was overly broad and could have unintended consequences on the municipal securities market as a whole.⁸³

One commenter “generally agree[d] with the proposal to have those trades

which can reasonably be reported within one minute be required by rulemaking to be reported within such time,”⁸⁴ but challenged the “benefit of an across-the-board shortening of reporting times and [had] concerns about the costs and risks associated with implementation.”⁸⁵ Another commenter questioned “what sort of benefit this almost-immediate reporting delivers or if the rule may very well adversely impact certain types of liquidity.”⁸⁶ One commenter stated that “[a]ccelerating the timeframe for trade reporting [would] not result in any additional protection for investors and may well further inhibit capital being deployed in the marketplace,”⁸⁷ further noting that “increasing the cost and compliance burden [would] impair liquidity and the willingness of firms to commit capital to their municipal business.”⁸⁸ A further commenter noted that the “transition to one-minute reporting has neither been adequately examined or justified”⁸⁹ and did not “believe that the proposed one-minute reporting rule [could] be adopted without exposing the broker-dealer community to significant liability and creating risk to the function of some fixed income markets”⁹⁰ and that “subjecting the fixed income market to trade reporting requirements that appear to be inspired by the equities market is misguided.”⁹¹ Building on its 2022 letter, an additional commenter reiterated that the “[p]roposals lack evidence of a market failure to justify such a change” and “[would] not provide a tangible benefit to investors.”⁹² This commenter also expressed the view that “regulatory changes based upon incomplete assumptions would be harmful to investors and threaten the participation of small and mid-sized broker-dealers.”⁹³ A commenter stated that the proposed rule change did “not provide evidence to support how the reporting change would result in a material

⁷³ *Id.* at 5392.

⁷⁴ See Section 4.3.2 of the Specifications for Real-Time Reporting of Municipal Securities Transactions; Exchange Act Release No. 55957 (June 26, 2007), 72 FR 36532 (July 3, 2007), File No. SR-MSRB-2007-01.

⁷⁵ See Notice, 89 FR at 5392.

⁷⁶ *Id.*

⁷⁷ See *supra* notes 4, 7, and 12. Separately, the MSRB published a request for information soliciting stakeholder input regarding the impact of MSRB rules on smaller regulated entities (“Small Firm RFI”) on December 4, 2023. Eight (8) of the comments received by the MSRB in response to the Small Firm RFI discussed the original proposed rule change or a draft version of the original proposed rule change previously published for comment. See letters to Ronald W. Smith, Corporate Secretary, MSRB, from: Mike Petagna, President, Amuni Financial, Inc. dated Jan. 8, 2024 (“Amuni RFI Letter”); Mr. Kamler, Sanderlin Securities LLC dated Jan. 26, 2024 (“Sanderlin Securities RFI Letter”); Robert S. Searle, President, Searle & Co., Inc. dated Feb. 16, 2024 (“Searle RFI Letter”); Brad

Harris, Director of Fixed Income—Municipal Bonds, Herold & Lantern Investments dated Feb. 22, 2024 (“HLI RFI Letter”); Jessica R. Giroux, General Counsel, ASA dated Feb. 26, 2024 (“ASA RFI Letter”); Mr. Decker, BDA dated Feb. 26, 2024 (“BDA RFI Letter”); Leslie M. Norwood, Managing Director and Associate General Counsel, Head of Municipal Securities, SIFMA dated Feb. 26, 2024 (“SIFMA RFI Letter”); and Stern Brothers & Co. dated Feb. 26, 2024 (“Stern Bros. RFI Letter”). The comment letters received in response to the Small Firm RFI are available at: <https://www.msrb.org/Regulatory-Documents?id=13895>.

⁷⁸ See *supra* note 10.

⁷⁹ See MSRB Letter at 4.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² See, e.g., letters from SIFMA; BDA; ICI; Dimensional Fund Advisors; Belle Haven; Bernardi Securities; Piper Sandler; LPL.

⁸³ See, e.g., letters from BDA, Noto, State of Florida, Sanderlin Securities, SIFMA, ASA, Falcon Square Capital.

⁸⁴ See BDA Letter at 1. BDA generally reiterated its position in the BDA OIP Letter and BDA Amendment No. 1 Letter.

⁸⁵ See BDA Letter at 1.

⁸⁶ See Noto Letter.

⁸⁷ See State of Florida Letter at 1.

⁸⁸ *Id.* at 2.

⁸⁹ See SIFMA Letter at 2.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² ASA Letter at 1. ASA generally reiterated its position in the ASA OIP Letter and ASA Amendment No. 1 Letter.

⁹³ *Id.* at 2. ASA included its 2022 comment letter which already explained that the “Proposals are notable in that they offer scant evidence for why current reporting requirements are inadequate or how investors would benefit by a shift to a mandated one-minute time frame.” *Id.* at 5–6.

improvement of the fixed-income securities market”⁹⁴ and that the proposed rule change “appear[ed] to extrapolate the effects of the 2005 change in reporting time . . . to support the claim that a further reduction in reporting time would provide more market transparency and immediate access to data for the remaining 26.3% of trades that were not reported to the MSRB within one minute during 2022.”⁹⁵ One commenter stated that the MSRB failed to “provide carefully detailed analysis of the clear and substantial benefit to the municipal securities marketplace;”⁹⁶ “provide adequate evidence upon which the SEC can reach a determination as to whether to approve or disapprove the proposed rule change;”⁹⁷ and “advance quantifiable data to support its assertion that investors will save millions of dollars through such radically reduced reporting times.”⁹⁸ A further commenter expressed “concern that the [proposed rule change] will expose broker-dealers to significant regulatory risk and clients to diminished liquidity and service from their broker-dealers.”⁹⁹ Another commenter expressed a positive view by stating that “transparency fosters a fair and efficient market and that market quality is improved when public information is disseminated evenly to all market participants”¹⁰⁰ enhancing “investors’ power to negotiate with dealers, leading to reduced transaction costs.”¹⁰¹ One commenter “question[ed] whether one-minute trade reporting is suitable across the board for all fixed income markets” and believed that the “current trade reporting framework already strikes an appropriate balance between transparency, the ability to reasonably comply, and market liquidity.”¹⁰² Additionally, this commenter noted that the proposed rule change “lack[ed] sufficient evidence and reasoning as to why shortening the reporting timeframe is necessary, much less achievable.”¹⁰³

In response to comments, the MSRB explained that one way to assess the magnitude of the benefits of the proposed rule change is to compare the amount investors are paying (or might

pay in the future as a result of rulemaking) to the amount they would otherwise pay in a more efficient market.¹⁰⁴ The MSRB further explained that when it previously shortened the trade reporting deadline from end-of-day to 15 minutes from the Time of Trade in 2005, the MSRB’s analysis of data collected showed a significant reduction in average customer trade effective spreads.¹⁰⁵ The MSRB also noted that its analysis also showed that effective spreads for customer trades continued to decline in the last decade with progressively faster trade reporting due to technology improvements undertaken by the industry to execute trades more quickly and efficiently but that this downward trend had become less pronounced in recent years.¹⁰⁶ The MSRB stated that it believes that it has appropriately demonstrated the estimated costs and benefits that the proposed rule change would likely provide to the municipal securities market¹⁰⁷ because the proposed rule change would result in reduced transaction costs for investors (*i.e.*, reduced effective bid-ask spread on customer trades) and increased trading volume from the effective spread reduction because investors are more likely to trade when the cost to trade is lowered.¹⁰⁸ Further, the MSRB explained that it expects that the universe of potentially benefited transactions and trading volume would be significantly larger than one commenter¹⁰⁹ described and that a shorter trade reporting window would likely result in yield curves that more accurately reflect the prevailing market conditions because of lower information lags in reported trade prices.¹¹⁰

ii. Impact on Competition and Liquidity

Some commenters expressed views that shortening the reporting timeframe disproportionately impacted less active and smaller dealers, potentially leading to a decline in liquidity, capital resources, and concentration of municipal bond trading among the largest dealers in the industry. One commenter noted that the proposed rule change “grossly underestimated the costs of the proposed rule”¹¹¹ and forecasted that the proposed rule change would put many firms out of

business.¹¹² Such commenter further explained that the “retail investor’s liquidity and negotiating power will be eliminated with the competitive landscape reduced to the largest of firms which do not negotiate with retail investors.”¹¹³ A further commenter raised concerns “that significant regulatory changes—particularly when based upon incomplete assumptions—would be harmful to investors and threaten the participation of small and mid-sized broker-dealers in these markets.”¹¹⁴ An additional commenter raised the concern that a “unilateral reduction to a one-minute reporting timeframe could create undue burdens on execution quality and liquidity with respect to large volume trades or trades in less liquid securities”¹¹⁵ because “dealers may have insufficient time to hedge their positions or allocate risk with respect to large-sized trades or transactions in thinly traded securities and therefore lead to less willingness by dealers to provide liquidity” for these types of trades.¹¹⁶ Another commenter noted that the proposed rule change “[p]unished”¹¹⁷ small broker-dealers and would “ultimately reduce liquidity for investors.”¹¹⁸ In response to comments, the MSRB stated that it believes that the potential adverse impacts on competition and liquidity are appropriately mitigated by the two exceptions from the one-minute reporting requirement included in the proposed rule change, which would allow dealers of all sizes, levels of market activity, manners of executing transactions, and business models to continue to engage in municipal securities activities to promote a fair, efficient, robust and more modern municipal securities market consistent with investor protection.¹¹⁹

iii. Technology Costs

Some commenters raised concerns that the proposed rule change would impose increased costs of new technology infrastructure. One commenter expressed the view that small firms that do not qualify for the limited trading exception would have to “implement more sophisticated and expensive automated reporting

⁹⁴ See Falcon Square Capital Letter at 1. Falcon Square Capital generally reiterated its position in the Falcon Square Capital Amendment No. 1 Letter.

⁹⁵ See Falcon Square Capital Letter at 1–2.

⁹⁶ See Belle Haven Letter at 3.

⁹⁷ *Id.* at 1.

⁹⁸ *Id.* Belle Haven generally reiterated its position in the Belle Haven Amendment No. 1 Letter.

⁹⁹ LPL OIP Letter at 1.

¹⁰⁰ See Dimensional Fund Advisors Letter at 1.

¹⁰¹ *Id.*

¹⁰² See FHN Financial OIP Letter at 2.

¹⁰³ *Id.*

¹⁰⁴ See MSRB Letter at 6.

¹⁰⁵ *Id.* at 6–7.

¹⁰⁶ *Id.* at 7.

¹⁰⁷ *Id.* at 6.

¹⁰⁸ *Id.* at 7.

¹⁰⁹ See Belle Haven Letter at 3.

¹¹⁰ See MSRB Letter at 8 (citing the Notice, 89 FR at 5395 n.74 and 5398).

¹¹¹ See Belle Haven Letter at 6.

¹¹² *Id.*

¹¹³ *Id.* at 5.

¹¹⁴ See ASA Letter at 9.

¹¹⁵ See ICI Letter at 3.

¹¹⁶ *Id.* at 2 n.4.

¹¹⁷ See Sanderlin Securities Letter at 3.

¹¹⁸ *Id.* at 3.

¹¹⁹ See MSRB Letter at 10.

systems”¹²⁰ that they estimated at half a million dollars each year¹²¹ which would be “cost prohibitive to smaller firms” and would lead to “curtail[ing] customer access to the fixed income securities market.”¹²² Another commenter noted that the “technology to report all transactions involving a manual component within five minutes does not currently exist and may never exist, given the structure of the market” and expressed the view that “members [would] need significant time to review systems to ensure that one-minute reporting can be accomplished; create systems, policies and procedures for manual trade indicators, and train staff” and also noted the “high costs of systems development” necessary to make operational changes to effect the original proposed rule change.¹²³ A further commenter explained that “[b]uilding compliant systems for all aspects of the Proposals [would] require major investments by dealers and vendors in technology, training, and revisions to supervisory procedures” and that “[i]mplementation [would] be especially challenging for smaller . . . members who have fewer resources to commit to not only these changes, but the plethora of other new rules and amendments on the regulatory horizon.”¹²⁴ Additionally, this commenter explained that many firms “rely on third-party vendors to report all or most of their trades to TRACE and RTRS.”¹²⁵ This commenter stated that “vendors that need to update their infrastructure to accommodate changing reporting timelines will pass on this expense to dealers that rely on their service.”¹²⁶

In response to comments, the MSRB observed that most small and mid-sized firms that would otherwise need to shoulder higher technology or service costs would likely qualify as dealer with limited trading activity for which the proposed exception from the one-minute reporting timeframe would apply.¹²⁷ The MSRB further explained that such firms would not need to obtain additional, and potentially more sophisticated, technology infrastructure or services beyond their current arrangements.¹²⁸ The MSRB stated that it believes that the potential adverse

impacts on competition and liquidity raised by some commenters are appropriately mitigated by the two exceptions from the one-minute reporting which would allow dealers of all sizes, levels of market activity, manners or executing transactions, and business models to continue to engage in municipal securities activities to promote a fair, efficient, robust and more modern municipal securities market consistent with investor protection.¹²⁹

B. General Comments on Exceptions to One-Minute Reporting

Commenters expressed several views relating to the exceptions. One commenter believes that the “current exceptions contained in the proposals represent essential elements to ensure industry compliance” and that “[w]ith the exceptions in place, the Proposals strike a reasonable balance between regulatory modernization and operational limitations which prevent may trades from meeting the one-minute reporting standard.”¹³⁰ This commenter further emphasized that “without the exceptions for dealers with limited trading activity and for trades with a manual component, the Proposals would be unworkable.”¹³¹ Another commenter stated that the exceptions are critical to protect smaller dealer members and would be required if the proposed rule change moves forward.¹³² A further commenter supported the manual exception and noted that the scope of the manual trade exception should be consistent between SROs.¹³³ One commenter, however, noted that the “exceptions do not appreciably alter market dynamics”¹³⁴ and expressed concern over the idea that either of the “exceptions could be reduced over time without being proposed for public comment”¹³⁵ which “would also set a troubling precedent that would allow SROs to implement changes without an evidentiary or legal justification for

doing so.”¹³⁶ One commenter advocated for the complete phase out of the exceptions so that all trades subject to the 15-minute reporting timeframe will be reported within one minute.¹³⁷ An additional commenter stated that its support for the original proposed rule change is conditioned on retaining the exceptions for firms with limited trading activity and for trades with a manual component.¹³⁸

In response to comments, the MSRB agreed that the exceptions are important components of the proposed rule change and agreed with commenters that asserted that the exceptions are critical to making the proposed rule change workable and provide for an orderly transition to a more rapid trade reporting paradigm¹³⁹ and noted that it “fully intends for the proposed new intra-day exceptions for trade reporting of municipal securities work in the same manner and at the same pace, and therefore consistent with, requirements for other fixed income securities.”¹⁴⁰ The MSRB further explained that “consideration of whether or when one or both of the proposed exceptions should be phased out is premature, because the MSRB currently lacks sufficient data so support such a decision.”¹⁴¹ The MSRB stated that it “intends to monitor trade reporting activity and potential impacts on the marketplace to determine whether any changes to the proposed rule change should be considered in the future.”¹⁴²

i. Trades With a Manual Component Exception

Commenters generally noted that the trades with a manual component exception balances shortening reporting requirements while avoiding undue disruptions to the municipal securities market. One commenter stated that it believed that the trades with a manual component exception is an “appropriate balance between shortening reporting timeframes and avoiding disruption to the marketplace or causing undue burdens.”¹⁴³ Another commenter requested that the MSRB should “implement a broad exception for manual trades.”¹⁴⁴ Several commenters raised questions about the application of the exception where manual steps may have been taken prior to trade execution but where the execution itself and the

¹²⁹ *Id.* at 10.

¹³⁰ See BDA Letter at 1.

¹³¹ See *id.*; BDA Amendment No. 1 Letter at 2 (expressing the view that the exceptions are made stronger by the changes made by Amendment No. 1).

¹³² See, e.g., SIFMA Letter at 2. SIFMA reiterated its position in the SIFMA OIP Letter and SIFMA Amendment No. 1 Letter at 2 (expressing the view that the proposed manual trade exception “is not a panacea since a mandatory one-minute requirement remains unworkable even for certain fully-electronic trades.”).

¹³³ See FIF I Letter at 2; FIF OIP Letter at 2 (expressing the view that the proposed manual trade exception “is important to avoid disruption to current trading practices for bonds.”).

¹³⁴ See ASA Letter at 1.

¹³⁵ *Id.* at 2.

¹³⁶ *Id.*

¹³⁷ See Dimensional Fund Advisors Letter at 2.

¹³⁸ See Piper Sandler OIP Letter at 1.

¹³⁹ See MSRB Letter at 11.

¹⁴⁰ *Id.* at 12.

¹⁴¹ *Id.* at 11.

¹⁴² *Id.*

¹⁴³ See ICI Letter at 3.

¹⁴⁴ See LPL OIP Letter at 2.

¹²⁰ See Falcon Square Capital Letter at 2. Falcon Square Capital reiterated its position in the Falcon Square Capital Amendment No. 1 Letter.

¹²¹ See Falcon Square Capital Letter at 2.

¹²² *Id.* at 6.

¹²³ See SIFMA Letter at 10.

¹²⁴ See BDA Letter at 4.

¹²⁵ *Id.* at 3.

¹²⁶ *Id.* at 4.

¹²⁷ See MSRB Letter at 9.

¹²⁸ *Id.*

subsequent trade reporting workflow may be fully automated.¹⁴⁵ Commenters provided examples where systems processing limitations would prevent certain fully automated trades to be reported within one minute.¹⁴⁶ Some commenters requested clarification in the context of dual registrants and situations where a dealer allocates a block trade to allocate trades.¹⁴⁷ One such commenter noted that “maintaining the reporting time at 15 minutes is necessary, considering the complexities involved in the manual trade reporting process.”¹⁴⁸

With respect to qualifying as a trade with a manual component, the MSRB reiterated that “the manual aspect of the trade workflow generally would only occur after the relevant Time of Trade.”¹⁴⁹ The MSRB explained that “where trade execution and reporting processes are fully electronic, a minimal triggering action (e.g., click “accept”) to prompt the electronic execution of a trade at the beginning of the process, by itself, typically would not be sufficient to constitute a manual step qualifying the trade for the manual trade exception.”¹⁵⁰ As it relates to system processing limitations, including trades involving large post-trade automated allocations, portfolio trades, trades involving batch processing, and trades where multiples systems are involved in a trade workflow, the MSRB stated that “analysis of such scenarios related to fully automated trades under the [proposed rule change] is likely to be highly fact specific.”¹⁵¹ Because it is a facts and circumstances determination, the MSRB further explained that it is impossible to create an exhaustive list of examples and that “dealers should document the circumstances giving rise to [any reporting] delays and consider potential alternatives for reasonable ways to improve the timing of trade reporting such circumstances.”¹⁵² The MSRB reminded dealers of the “overarching obligation to report trades as soon as practicable in light of the effects of such circumstances or justification”¹⁵³ even if not within the

applicable one-minute timeframe.¹⁵⁴ The MSRB further explained that “failure to report such trades as soon practicable could be a factor weighing against the determination of whether the exceptional circumstances or reasonable justification provisions of the [proposed rule change] would be available to a dealer making such late reports.”¹⁵⁵ With respect to large or block transaction, the MSRB explained that depending on the specific facts and circumstances, “where a dealer executes a large or block transaction that requires allocations of portions of the trade to individual accounts, unless the initial large or block trade independently qualifies for the manual trade exception and absent another exception, the large or block transaction normally would not qualify for the manual trade exception and instead would be subject to the one-minute reporting requirement.”¹⁵⁶ The MSRB further noted that the “manual trade exception may, however, be available for any resulting allocations to individual accounts that may be required to be reported and such reporting involves manual input or other manual steps.”¹⁵⁷

a. Phase-In Period

Several commenters addressed the phase-in of the shortening reporting timeframe for trades with a manual component.¹⁵⁸ Some commenters requested that the MSRB propose for notice and comment each reduced outer limit timeframe for the trades with a manual component exception to allow market participants the opportunity to submit valuable data and comment prior to the MSRB shortening the reporting timeframe.¹⁵⁹ One commenter expressed the view that this exception was not a true exception¹⁶⁰ and requested that the MSRB “collect data to support a reduction in reporting time for manual trades before it proposes a rule to do so”¹⁶¹ as, according to this commenter, the MSRB did not “cite a scintilla of statistical or objective support for the need to “phase in” a

reduction of reporting for manual reporters”¹⁶² or “provide the SEC with evidence that manual reporters are not currently reporting as fast as practicable.”¹⁶³ This commenter also raised the concern that the phase-in period may eliminate small firms which are incapable of meeting the phased-in time periods.¹⁶⁴ One commenter noted uncertainty regarding the technological capabilities to meet the proposed phase-in timeframes, and requested the MSRB to undertake ongoing monitoring, analysis, and stakeholder engagement.¹⁶⁵ A further commenter requested that the MSRB “[e]xamine impacts to liquidity, depth, concentration, and transparency prior to decreasing reporting times to shorter intervals to ensure markets are not harmed.”¹⁶⁶ One commenter also expressed being troubled by the language of the manual trade exception because it “suggests the possibility of reassessing the reporting timeframe, potentially leading to further reductions or even the elimination of the manual trade exception altogether.”¹⁶⁷

The MSRB noted that “it does not have specific evidence that dealers are currently, as a matter of practice, reporting trades less rapidly than as soon as practicable”¹⁶⁸ but “believes that the new requirement for reporting as soon as practicable would have the effect of increasing the proportion of trades being reported within shorter timeframes than they currently are, without regard to a one-minute, five-minute or 15-minute deadline, potentially translating into significant improvement in market-wide average reporting times.”¹⁶⁹ The MSRB also stated that it “would monitor the implementation of the [proposed rule change] and, going forward, would analyze trade data related to the operation of the proposed two new exceptions to, among other things, determine whether the eventual five-minute trade reporting timeframe that would become applicable after two years continues to be feasible and appropriate in light of the empirical data collected through the earlier phases

¹⁴⁵ See, generally, BDA Letter; FIF I Letter; ICI Letter; SIFMA Letter; ASA Letter.

¹⁴⁶ See, e.g., BDA Letter at 4; Searle RFI Letter at 2; SIFMA Letter at 3, 7–9; FIF I Letter at 3.

¹⁴⁷ See, e.g., BDA Letter at 4; SIFMA Letter at 7; Falcon Square Capital Letter at 3–4; FIF I Letter at 3; LPL OIP Letter at 2; SIFMA OIP Letter at 5; BDA OIP Letter at 1–2.

¹⁴⁸ See ASA Letter at 2.

¹⁴⁹ See MSRB Letter at 13 (citing Notice, 89 FR 5386–87).

¹⁵⁰ *Id.* at 13.

¹⁵¹ *Id.* at 14.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ See MSRB Letter at 15 and accompanying notes 55 through 57 (citing the Notice, 89 FR at 5389).

¹⁵⁷ *Id.*

¹⁵⁸ See, e.g., BDA Letter at 3; ICI Letter at 3–4; Falcon Square Capital Letter at 4; Falcon Square Capital Amendment No. 1 Letter at 3–4; SIFMA Letter at 6; SIFMA OIP Letter at 6; SIFMA Amendment No. 1 Letter at 3; ASA OIP Letter at 2; ASA Amendment No. 1 Letter at 1; Belle Haven Letter at 5–9; Belle Haven Amendment No. 1 at 3–4; BDA OIP Letter at 3, 5; LPL OIP Letter at 2.

¹⁵⁹ *Id.*

¹⁶⁰ See Belle Haven Letter at 6.

¹⁶¹ *Id.* at 9.

¹⁶² *Id.* at 7.

¹⁶³ *Id.* at 7.

¹⁶⁴ *Id.* at 5.

¹⁶⁵ See SIFMA Letter at 6–7. See generally ICI Letter at 3–4 (noting potential impacts of implementing the proposed phase-in timeframes and requesting that the MSRB propose for notice and comment each reduced outer limit timeframe to allow market participants the opportunity to submit valuable data and comments prior to potentially shortening reporting timeframes).

¹⁶⁶ See LPL OIP Letter at 2.

¹⁶⁷ See ASA Letter at 2.

¹⁶⁸ See MSRB Letter at 17.

¹⁶⁹ *Id.*

of implementation.”¹⁷⁰ To address concerns expressed by commenters regarding potential difficulties in meeting the shortened reporting timeframes and make the necessary changes to processes and technology to achieve such shortened timeframes, the MSRB has “determined to modify the pace of phasing-in the shortened reporting timeframe for trades with a manual component to extend the period during which such trades would be reportable by no later than 10 minutes after the Time of Trade from one year to two years.”¹⁷¹ To alleviate commenters concerns related to the elimination of the of the trades with a manual component exception, the MSRB explained that the proposed rule change “sets out a phased-in implementation of the exception for manual trades that would provide for an ultimate five-minute timeframe for the reporting of such trades. No further reductions in such timeframe, and no elimination of the manual trade exception could be possible without additional formal rulemaking by the MSRB that would be filed with the Commission, and any such change would be subject to the required notice and comment process under Section 19 of the Exchange Act.”¹⁷²

b. Manual Trade Indicator

Several commenters addressed the manual trade indicator.¹⁷³ Commenters requested that the trade indicator apply instead to fully automated trades subject to the one-minute reporting requirement.¹⁷⁴ One commenter recommended that the MSRB default the manual trade indicator for any transaction that is reported initially through the RTRS web portal.¹⁷⁵ Commenters requested that the MSRB institute an interim period where firms are permitted, but not required, to report the manual trade indicator.¹⁷⁶ One commenter also requested clarification on the use of a portfolio trade modifier in specific scenarios.¹⁷⁷

After considering comments, the MSRB explained that “to the extent that these trades are fully automated—both the execution and the trade reporting—the manual trade indicator would not apply and should not be used, and the exception for trades with a manual component also would not apply.”¹⁷⁸ The MSRB further noted that since “dealers are already successfully processing other trade indicators that must be applied on an individualized basis in the context of manual and electronic trades[,] the MSRB believes that existing processes can be modified to include the manual trade indicator with only limited additional effort and expense.”¹⁷⁹ In response to the requested interim period for optional use, the MSRB “contemplates providing dealers with sufficient time to implement and test the use of the indicator and does not intend at this time to provide an optional reporting period.”¹⁸⁰ Additionally, the MSRB explained that since “one of the intended purposes of the manual trade indicator is to provide regulators with the information necessary to make thoughtful and pragmatic changes and identify roadblocks to achieving faster trade reporting for trades with a manual component”¹⁸¹ the MSRB stated that it “will be using the manual trade indicator to assess whether taking further action in the course of such phase-in might be warranted.”¹⁸²

C. Limited Trading Activity Exception

Several commenters addressed the limited trading activity exception.¹⁸³ One commenter noted that the “[limited trading activity] exception is appropriately based on trade numbers that are correctly sized to protect minority, veteran and women owned business enterprises and small dealers from incurring the significant costs associated with the proposed rule”¹⁸⁴

rapid execution and frequent communications on multiple transactions with multiple counterparties, with the dealer having to book and report those transactions manually. In response, the MSRB clarified that the “Notice was not intended to create a requirement for portfolio trades to be reported with a trade indicator under MSRB Rule G–14, and no such portfolio indicator is proposed or would be required pursuant to the proposed rule change.” See MSRB Letter at 16. The MSRB further explained “that it has not made a determination as to whether an “away from market” indicator would be required in connection with any particular portfolio transaction.”). *Id.* at 17.

¹⁷⁸ See MSRB Letter at 14.

¹⁷⁹ *Id.* at 18–19.

¹⁸⁰ *Id.* at 24.

¹⁸¹ *Id.* at 18 n.66.

¹⁸² *Id.*

¹⁸³ See, e.g., SIFMA Letter; BDA Letter; Falcon Square Capital Letter; Belle Haven Letter; FIF I Letter. See also BDA OIP Letter; SIFMA OIP Letter.

¹⁸⁴ See SIFMA Letter at 9.

while the proposed two-year look back period “[would] allow newly impacted members some time to attempt to implement systems to attempt to achieve compliance.”¹⁸⁵ Another commenter supported the limited trading activity exception, believing many firms in the market will benefit greatly from this exception.¹⁸⁶ An additional commenter expressed the view that the proposed 1,800-trade threshold is “far too low”¹⁸⁷ and requested that the MSRB either significantly expand the threshold or conduct further analysis and provide data to support the 1,800 threshold.¹⁸⁸

After considering comments received, the MSRB determined to increase the threshold to 2,500 trades.¹⁸⁹ As explained by the MSRB, “the revised 2,500 threshold is expected to exempt a clear majority of dealers, i.e., 476 out of 651 dealers or approximately 73 percent of dealers based on 2021 and 2022 trade reporting data and these dealers would remain eligible to report their trades in 15 minutes or less.”¹⁹⁰ As stated by the MSRB, “these limited activity dealers account for 1.4 percent of total trades and 2.3 percent of the total par value traded, and therefore would have a

¹⁸⁵ *Id.*

¹⁸⁶ See BDA Letter at 2.

¹⁸⁷ See Falcon Square Capital Letter at 3.

¹⁸⁸ *Id.* at 3.

¹⁸⁹ See MSRB Letter at 22 n.81 (explaining that “upon further review of the methodology used for proposing a 1,800-trade threshold for qualifying for the dealer with limited trading activity exception in the original proposed rule change, the MSRB has determined to increase the threshold to 2,500 trades based on a modification of its methodology described below. In establishing the original proposed threshold of 1,800 trades, the MSRB had used an approach consistent with other instances where MSRB rules and related transparency activities are based on inter-dealer trade report activity that rely solely on the sell-side inter-dealer trade reports so as to avoid, for those specific purposes, potential double counting if both the sell-side and buy-side were to be used. For example, the manner in which the MSRB disseminates trade reports for compared inter-dealer trades and assesses its transaction and trade count fees for inter-dealer trades under MSRB Rule A–13(d) is based solely on sell-side trade reports for the reasons described in Amendment No. 1. As a result, the calculations discussed in the MSRB Filing Notice underlying the 1,800-trade threshold in the proposed definition of “dealer with limited trading activity” was lower and did not fully account for inter-dealer trade reports since only the sell-side inter-dealer trade reports were taken into account. In order to maintain compatibility with the plain meaning of the language of the MSRB’s proposed definition of “dealer with limited trading activity,” the MSRB has recalculated the applicable threshold for such definition to be 2,500 trades, taking into account both sell-side and buy-side inter-dealer trade reports together with reports of dealer trades with customers, regardless of whether the dealer bought or sold in the customer transaction.”). See also Amendment No. 1.

¹⁹⁰ See MSRB Letter at 23.

¹⁷⁰ *Id.* at 20.

¹⁷¹ *Id.*

¹⁷² See MSRB Letter at 20 (citing 15 U.S.C. 78s).

¹⁷³ See BDA Letter at 3; SIFMA Letter at 9; SIFMA OIP Letter at 7–8; FIF Letter I at 3–4; FIF Letter II generally.

¹⁷⁴ See BDA Letter at 3; SIFMA Letter at 9; SIFMA OIP Letter at 7–8.

¹⁷⁵ See FIF I Letter at 4.

¹⁷⁶ *Id.* at 6; SIFMA OIP Letter at 8.

¹⁷⁷ See generally FIF I Letter (scenarios where a firm corrects a technical issue and then submits automatically); FIF II Letter (consisting of examples of such scenarios and requesting corresponding clarification); FIF OIP Letter (FIF requested clarification on the use of a portfolio trade modifier to RTRS where a dealer receives a large order or a trade list resulting in a portfolio of trades with potentially numerous unique securities involving

minimal impact on market transparency.”¹⁹¹

D. Consistency in Implementation

Commenters recommended an implementation path for municipal securities that is staggered with other fixed income securities.¹⁹² In response to comments, the MSRB “emphasize[d] that greater consistency in implementing changes across the various fixed income markets can be better achieved if the proposed requirements are applied to the entire fixed income industry at the same time. Consistency, not only in reporting requirements but also implementation of those requirements, helps avoid confusing and different reporting standards for the industry.”¹⁹³

E. Implementation Period

Two commenters requested a two-year implementation period and requested that the MSRB remain open to the creation of FAQs or the provision of implementation guidance to achieve greater compliance.¹⁹⁴ One commenter requested an eighteen-month implementation period from the date the MSRB publishes technical specifications and guidance, requested a testing period with additional supports and enhancements ahead of final implementation, and a transitional period during which dealers would not be required to include the manual indicator on trades with a manual component.¹⁹⁵ In response to comments, the MSRB stated that it “continues to intend to maintain an implementation schedule for the proposed rule change that is aligned with the implementation for other fixed income securities.”¹⁹⁶ The MSRB also explained that it will “endeavor to publish updated technical specifications as far as possible in advance of the effective date(s) and will work with dealers to provide interpretive guidance, where needed”¹⁹⁷ as is generally the protocol for RTRS and Information Facility changes and “will facilitate free testing that would include test CUSIP numbers and other appropriate support to ensure that all dealers have a significant opportunity to prepare their systems and processes to achieve full compliance with the requirements of the

proposed rule change, if approved.”¹⁹⁸ In response to the requested interim period for optional use of the manual trade indicator, the MSRB “contemplates providing dealers with sufficient time to implement and test the use of the indicator and does not intend at this time to provide an optional reporting period.”¹⁹⁹

F. Consistency With the Act

Some commenters challenged the proposed rule change as circumventing regulatory obligations and requested that the MSRB conduct further analysis before implementation of the proposed rule change.²⁰⁰ One commenter expressed the view that the MSRB relied on “conclusory statements without background data in support”²⁰¹ and requested that the Commission deny and return the proposed rule change to the MSRB for further study and consideration.²⁰² Another commenter asserted that the Commission “want[ed] to avoid conducting a robust economic cost/benefit analysis”²⁰³ and “strongly recommend[ed] these Proposals be abandoned in their entirety.”²⁰⁴ An additional commenter strongly encouraged the Commission to require the MSRB to revisit the proposed rule change in order to “consider the economic challenges of smaller firms before modifying the current rule.”²⁰⁵ Another commenter raised issues regarding whether the proposed rule change conforms with the requirements of the Administrative Procedure Act (“APA”).²⁰⁶ Some commenters defended the process undertaken by the MSRB in connection with the proposed rule change.²⁰⁷

In response, the MSRB stated that it “is confident that the current rulemaking has been undertaken fully in compliance with applicable statutory and regulatory requirements and has had the benefit of fulsome input from market participants and is backed by extensive data analysis.”²⁰⁸ The MSRB further stated that while not statutorily required, the MSRB “published a draft version of the proposal for comment in October 2022, including a preliminary economic analysis of such draft

proposal, and received over 50 comment letters in response.”²⁰⁹ The MSRB explained how the MSRB “revised the draft version in response to comments received and, upon approval by the MSRB’s board of directors, filed it with the Commission as the original proposed rule change as required under Section 19(b) of the Exchange Act. Also as required by Section 19(b) of the Exchange Act, the Commission published the MSRB Filing Notice for comment.”²¹⁰ The MSRB further explained how, in response to comments received, the Commission instituted proceedings to obtain further input on the original proposed rule change and the MSRB has now addressed the comments received on the MSRB Filing Notice in this letter.”²¹¹ The MSRB further stated that “[i]n part due to such extensive input, the MSRB has determined to file Amendment No. 1 to the original proposed rule change.”²¹² The MSRB further stated that “while the MSRB has consulted with FINRA and the Commission throughout this rulemaking process, the MSRB board of directors and staff have exercised their independent judgment in formulating the proposed rule change, which represents the culmination of MSRB deliberation on this topic stretching back to 2013.”²¹³

IV. Discussion and Commission Findings

The Commission has carefully considered the proposed rule change, as well as comment letters received, and the MSRB Letter. The Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to the MSRB.

In particular, the Commission believes that the proposed rule change is consistent with the provisions of Section 15B(b)(2)(C) of the Exchange Act and the rules and regulations thereunder.²¹⁴ Section 15B(b)(2)(C) of the Exchange Act provides, in part, that the MSRB’s rules shall be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing

¹⁹¹ *Id.* at 23 (referring to Table 2 in Amendment No. 1).

¹⁹² See, e.g., BDA Letter at 4; FIF I Letter at 5–6; ICI Letter at 2; SIFMA Letter at 10.

¹⁹³ See MSRB Letter at 12.

¹⁹⁴ See BDA Letter at 4; SIFMA Letter at 10.

¹⁹⁵ See FIF I Letter at 5–7; SIFMA OIP Letter at 8.

¹⁹⁶ See MSRB Letter at 24.

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ See generally Belle Haven Letter; ASA Letter; ASA OIP Letter; Falcon Square Capital Letter.

²⁰¹ See Belle Haven Letter at 2.

²⁰² *Id.*

²⁰³ See ASA Letter at 3.

²⁰⁴ *Id.*

²⁰⁵ See Falcon Square Capital Letter at 6.

²⁰⁶ See ASA Letter at 3; ASA OIP Letter at 2.

²⁰⁷ See, e.g., Bernardi Securities OIP Letter at 2; Piper Sandler OIP Letter at 1–2.

²⁰⁸ See MSRB Letter at 24.

²⁰⁹ *Id.* at 24–25. All comment letters received in response to the 2022 Request for Comment are available at <https://www.msrb.org/sites/default/files/2023-03/All-Comments-to-Notice-2022-07.pdf>.

²¹⁰ See MSRB Letter at 25.

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.* at 25 n.95 (listing MSRB Notice 2013–02 (Jan. 17, 2013); MSRB Notice 2013–14 (July 31, 2013); MSRB Notice 2014–14 (Aug. 13, 2014)).

²¹⁴ 15 U.S.C. 78o–4(b)(2)(C).

information with respect to, and facilitating transactions in municipal securities, to remove impediments to and perfect the mechanism of a free and open market in municipal securities, and, in general, to protect investors and the public interest.²¹⁵

The Commission believes that the proposed rule change is consistent with the Exchange Act because the proposed rule change is reasonably designed to remove impediments to and perfect the mechanism of a free and open market in municipal securities by bringing about greater market transparency through more timely disclosures and dissemination of information provided through the RTRS. Accordingly, the Commission finds that the proposed rule change is consistent with Section 15B(b)(2)(C) of the Act, as further described below, because the proposed rule change will (i) promote just and equitable principles of trade; (ii) foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities and municipal financial products; (iii) remove impediments to and perfect the mechanism of a free and open market in municipal securities and municipal financial products; and (iv) protect investors and the public interest.

A. Promote Just and Equitable Principles of Trade

The Commission finds the proposed rule change will promote just and equitable principles of trade by providing the market with more timely pricing information. As noted by the MSRB, some market professionals may in some circumstances have better or more rapid access to information about trade prices which retail investors do not have access.²¹⁶ The Commission believes that such reduced timeframe for trade reporting would improve market transparency by reducing information asymmetries between market participants and enhancing investor confidence in the market. The Commission also anticipates that the MSRB will monitor trade reporting activity and potential impacts on the marketplace to determine whether any changes to the proposed rule change should be considered in the future. The Commission will consider any future proposed rule changes filed with the Commission.

B. Foster Cooperation and Coordination

The Commission finds that the proposed rule change would foster cooperation and coordination between the SEC, the MSRB, and FINRA by establishing consistent trade reporting requirements across various classes of fixed income securities. As noted by the MSRB, consistent trade reporting requirements reduce the risk of potential confusion and may reduce compliance burdens resulting from inconsistent obligations and standards for different classes of securities.²¹⁷ A similar proposed rule change by FINRA, on which the MSRB closely coordinated with FINRA,²¹⁸ would result in a consistent standard for trade reporting for municipal securities and the TRACE-eligible securities covered by the FINRA proposed rule change.²¹⁹ Accordingly, the Commission believes that the proposed rule change will provide regulatory clarity and would foster cooperation and coordination between the MSRB and FINRA by establishing consistent trade reporting requirements across various classes of fixed income securities. Consistent trade reporting requirements for municipal securities covered by the proposed rule change and the TRACE-eligible securities covered by the FINRA proposed rule change also may reduce compliance burdens resulting from inconsistent obligations and standards for different classes of fixed income securities. Additionally, the Commission finds that the proposed rule change will allow the municipal securities market to produce more timely transaction data which will enhance surveillance of the market by enforcement agencies.

C. Remove Impediments to and Perfect the Mechanism of a Free and Open Market in Municipal Securities and Municipal Financial Products

The Commission finds that the proposed rule change would remove impediments to, and perfect the mechanism of, a free and open market in municipal securities by making

publicly available more timely transaction data at which municipal securities transactions are executed. As noted by the MSRB, prices at which transactions are executed is central to fairly priced municipal securities and a dealer's ability to make informed quotations.²²⁰ The Commission believes that the proposed rule change could mitigate certain information asymmetries that may exist, thereby enabling market participants to make more informed decisions. Further, the proposed exceptions reasonably balance the benefits to market participants of increased transparency while mitigating commenters' concern of a shortened trade reporting deadline. In this regard, the proposed rule change is reasonably designed to not permit unfair discrimination between customers, issuers, brokers, or dealers.

D. Protect Investors, Municipal Entities, Obligated Persons, and the Public Interest

The Commission finds that the proposed rule change will protect investors and the public interest by increasing market transparency and providing the market with more efficient pricing information.

In approving the proposed rule change, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation.²²¹ Exchange Act Section 15B(b)(2)(C)²²² requires that MSRB rules not be designed to impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.

The Commission does not believe that the proposed rule change would impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act because the proposed rule change takes into account competitive and liquidity concerns that could arise as a result of the costs associated with complying with a shortened reporting timeframe that could lead some dealers to exit the market, curtail their activities or consolidate with other firms. The MSRB has made efforts to minimize the impact of the proposed rule change on dealers in response to commenters including: (i) amending the definition of a dealer with limited trading activity in proposed subparagraph (d)(xi) of Rule G-14 RTRS Procedures by increasing the threshold for qualifying as a dealer with limited trading activity from 1,800 transactions to 2,500 transactions; and (ii) extending

²¹⁷ *Id.*

²¹⁸ The Commission did not direct the MSRB to file the proposed rule change and is not using the MSRB as a conduit to enact the proposed rule change. One commenter cites a speech by the Chair in stating to the contrary, but that speech does not specifically address the RTRS trade reporting timeframe at all. See ASA Amendment No. 1 Letter at 2 n.4 (citing Gary Gensler, Chair, Securities and Exchange Commission, Prepared Remarks before SEC Speaks: U.S. Capital Markets and the Public Good (Apr. 2, 2024) (transcript available at <https://www.sec.gov/newsroom/speeches-statements/prepared-remarks-sec-speaks-us-capital-markets-public-good>). And, in any event, the speech reflects the views of the Chair alone, not the Commission.

²¹⁹ See *supra* note 15.

²²⁰ See Notice, 78 FR at 5393.

²²¹ 15 U.S.C. 78c(f).

²²² 15 U.S.C. 78o-4(b)(2)(C).

²¹⁵ *Id.*

²¹⁶ See Notice, 89 FR at 5393.

the phase-in period for the manual trade exception in proposed new Supplementary Material .02(b) of Rule G–14 RTRS Procedures by one additional year. While the MSRB does not intend at this time to provide an interim period for optional use of the manual trade indicator, the MSRB intends to provide a sufficient implementation timeframe, publish updated technical specifications and will work with dealers to provide interpretive guidance, facilitate free testing and other appropriate support to ensure that all dealers have significant opportunity to prepare systems and processes to achieve full compliance with the proposed rule change.²²³ The Commission believes that the MSRB, through its responses and through proposed changes in Amendment No. 1 has addressed commenters' concerns.

The Commission has also reviewed the record for the proposed rule change and notes that the record does not contain any information to indicate that the proposed rule change would have a negative effect on capital formation. Further, the Commission finds that the possible increased investor protections offered by reducing the timeframe for trade reporting could foster greater faith in the integrity of the municipal securities market, increasing participation in this market, thereby increasing capital formation.

The Commission also finds that the proposed rule change includes provisions that help promote efficiency. In particular, the Commission believes that the reduced timeframe for trade reporting could further reduce information asymmetries between market professionals and retail investors by increasing access to more timely information about executed transactions.

For the reasons noted above, the Commission believes that the proposed rule change is consistent with the Act.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,²²⁴ that the proposed rule change (SR–MSRB–2024–01), as modified by Amendment No. 1, be, and hereby is, approved.

For the Commission, pursuant to delegated authority.²²⁵

Vanessa A. Countryman,
Secretary.

[FR Doc. 2024–22028 Filed 9–25–24; 8:45 am]

BILLING CODE 8011–01–P

²²³ See MSRB Letter at 24.

²²⁴ 15 U.S.C. 78s(b)(2).

²²⁵ 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 12554]

Notice of Public Meeting: International Information and Communications Policy Division Stakeholder Briefing

ACTION: Notice of public meeting.

SUMMARY: The State Department will hold a public meeting at 1 p.m.–2:30 p.m. (ET) on WebEx with the Bureau of Cyberspace and Digital Policy's International Information and Communications Policy (CDP/ICP) division. The purpose of the meeting is to brief stakeholders on CDP/ICP's past and upcoming international engagements. These include engagement at the International Telecommunication Union (ITU), the Organization of American States Inter-American Telecommunication Commission (CITEL), the Organization for Economic Cooperation and Development (OECD), the Asia Pacific Economic Cooperation (APEC) Forum Telecommunications and Information Working Group, the Group of Seven (G7) Digital & Tech Working Group, the Group of Twenty (G20) Digital Economy Task Force, and other multilateral processes and bilateral digital and ICT dialogues.

DATES: The meeting will be on October 9, 2024.

FOR FURTHER INFORMATION CONTACT: Please contact Coreene White, Foreign Affairs Officer, CDP/ICP, at WhiteCE@state.gov or 771–205–9909.

SUPPLEMENTARY INFORMATION: Additional information about the Bureau of Cyberspace and Digital Policy is accessible at <https://www.state.gov/bureaus-offices/deputy-secretary-of-state/bureau-of-cyberspace-and-digital-policy/>.

We encourage anyone wanting to attend this virtual meeting to register using the following link by 5 p.m. Monday, October 7: <https://statedept.webex.com/statedept/j.php?MTID=m5a8fd865411e9795f1b79405cceed2ed>.

Requests for reasonable accommodation made after Wednesday, October 2 will be considered but might not be able to be accommodated. The public may have an opportunity to provide comments at this meeting.

Agenda

Wednesday, October 9, 2024, at 1:00 p.m. (ET)

Opening Remarks
Briefings on CDP/ICP's past and upcoming activities
Public Comment

Adjournment

Stephan A. Lang,

U.S. Coordinator and Deputy Assistant Secretary, International Information and Communications Policy, Bureau of Cyberspace and Digital Policy, Department of State.

[FR Doc. 2024–21987 Filed 9–25–24; 8:45 am]

BILLING CODE 4710–10–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 290 (Sub-No. 5) (2024–4)]

Quarterly Rail Cost Adjustment Factor

AGENCY: Surface Transportation Board.

ACTION: Approval of rail cost adjustment factor.

SUMMARY: The Surface Transportation Board has adopted the fourth quarter 2024 Rail Cost Adjustment Factor and cost index filed by the Association of American Railroads.

DATES: *Applicability Date:* October 1, 2024.

FOR FURTHER INFORMATION CONTACT: Pedro Ramirez, (202) 245–0333. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245–0245.

SUPPLEMENTARY INFORMATION: The rail cost adjustment factor (RCAF) is an index formulated to represent changes in railroad costs incurred by the nation's largest railroads over a specified period of time. The Surface Transportation Board (Board) is required by law to publish the RCAF on at least a quarterly basis. Each quarter, the Association of American Railroads computes three types of RCAF figures and submits those figures to the Board for approval. The Board has reviewed the submission and adopts the RCAF figures for the fourth quarter of 2024. The fourth quarter 2024 RCAF (Unadjusted) is 0.961. The fourth quarter 2024 RCAF (Adjusted) is 0.375. The fourth quarter 2024 RCAF–5 is 0.354. Additional information is contained in the Board's decision, which is available at www.stb.gov.

Decided: September 20, 2024.

By the Board, Board Members Fuchs, Hedlund, Primus, and Schultz.

Zantori Dickerson,
Clearance Clerk.

[FR Doc. 2024–21985 Filed 9–25–24; 8:45 am]

BILLING CODE 4915–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Actions Taken at the September 12, 2024 Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: As part of its regular business meeting held on September 12, 2024, in Baltimore, Maryland, the Commission approved the applications of certain water resources projects and took additional actions, as set forth in the **SUPPLEMENTARY INFORMATION** below.

DATES: September 12, 2024.

ADDRESSES: Susquehanna River Basin Commission, 4423 N Front Street, Harrisburg, PA 17110-1788.

FOR FURTHER INFORMATION CONTACT:

Jason E. Oyler, General Counsel and Secretary, telephone: (717) 238-0423, ext. 1312, fax: (717) 238-2436; email: joyler@srbc.gov. Regular mail inquiries may be sent to the above address. See also the Commission website at www.srbc.gov.

SUPPLEMENTARY INFORMATION: In addition to the actions taken on projects identified in the summary above, these actions were also taken: (1) adopted a preliminary Fiscal Year 2026 budget; (2) unanimously adopted the member jurisdiction allocation requests for Fiscal Year 2026; (3) adopted a final rulemaking for establishing bid protest procedures, memorializing the Commission's Dry Cooling Resolution and other changes to Part 801; (4) approved four grant amendments; and (5) actions on 24 regulatory program projects.

Project Applications Approved

1. *Project Sponsor and Facility:* Amazon Data Services, Inc. Project Facility: PHL100 Data Center Campus, Salem Township, Luzerne County, Pa. Application for consumptive use of up to 0.060 mgd (30-day average).

2. *Project Sponsor and Facility:* Ashland Area Municipal Water Authority, Butler Township, Schuylkill County, Pa. Application for renewal of groundwater withdrawal of up to 0.115 mgd (30-day average) from Well 5 (Docket No. 19931101). *Service area is located in an Environmental Justice area.*

3. *Project Sponsor:* Borough of Middletown. Project Facility: Middletown Water System, Borough of Middletown, Dauphin County, Pa. Application for renewal of groundwater withdrawal of up to 1.070 mgd (30-day average) from Well 6 (Docket No.

19970702). *Service area is located in an Environmental Justice area.*

4. *Project Sponsor and Facility:* Caernarvon Township Authority, Caernarvon Township, Berks County, Pa. Application for renewal of groundwater withdrawal of up to 0.317 mgd (30-day average) from Well 8 (Docket No. 19940902). *Service area is located in an Environmental Justice area.*

5. *Project Sponsor and Facility:* Chesapeake Appalachia, L.L.C. (Loyalsock Creek), Forksville Borough, Sullivan County, Pa. Application for renewal and modification of surface water withdrawal of up to 1.500 mgd (peak day) (Docket No. 20190903).

6. *Project Sponsor and Facility:* Clear Water Technology, LLC (Middle Branch Wyalusing Creek), Forest Lake Township, Susquehanna County, Pa. Application for surface water withdrawal of up to 1.440 mgd (peak day).

7. *Project Sponsor and Facility:* Dillsburg Area Authority, Franklin Township, York County, Pa. Application for renewal of groundwater withdrawal of up to 0.199 mgd (30-day average) from Well 3 (Docket No. 20081207).

8. *Project Sponsor:* Greater Hazleton Community-Area New Development Organization, Inc. Project Facility: CAN DO, Inc.—Corporate Center, Butler Township, Luzerne County, Pa. Application for renewal of groundwater withdrawal of up to 0.547 mgd (30-day average) from Well 1 (Docket No. 20090309).

9. *Project Sponsor and Facility:* Jersey Shore Area Joint Water Authority, Pine Creek Township, Clinton County, Pa. Application for groundwater withdrawal of up to 0.452 mgd (30-day average) from Pine Creek Well 1, which is an increase of the quantity established in Certificate of Registration No. GF-202012137.

10. *Project Sponsor and Facility:* JKLM Energy, LLC (Mill Creek), Rutland Township, Tioga County, Pa. Application for surface water withdrawal of up to 0.600 mgd (peak day).

11. *Project Sponsor and Facility:* JKLM Energy, LLC (Tioga River), Lawrenceville Borough, Tioga County, Pa. Application for renewal with an increase of surface water withdrawal of up to 1.800 mgd (peak day) (Docket No. 20230610).

12. *Project Sponsor and Facility:* Municipal Authority of the Borough of Mansfield, Richmond Township, Tioga County, Pa. Application for renewal of groundwater withdrawal of up to 0.173

mgd (30-day average) from Well 1 (Docket No. 19940707).

13. *Project Sponsor and Facility:* Pennsylvania General Energy Company, L.L.C. (Loyalsock Creek), Plunketts Creek Township, Lycoming County, Pa. Application for renewal of surface water withdrawal of up to 2.000 mgd (peak day) (Docket No. 20231213).

14. *Project Sponsor:* The Procter & Gamble Paper Products Company. Project Facility: Mehoopany Plant, Washington Township, Wyoming County, Pa. Application for renewal of consumptive use of up to 2.750 mgd (peak day) (Docket No. 19940704).

15. *Project Sponsor and Facility:* Repsol Oil & Gas USA, LLC (Lycoming Creek), McIntyre Township, Lycoming County, Pa. Application for renewal of surface water withdrawal of up to 2.000 mgd (peak day) (Docket No. 20190910).

16. *Project Sponsor and Facility:* Seneca Resources Company, LLC (Marsh Creek), Delmar Township, Tioga County, Pa. Application for renewal of surface water withdrawal of up to 0.499 mgd (peak day) (Docket No. 20190911).

17. *Project Sponsor and Facility:* Shrewsbury Borough, York County, Pa. Application for renewal of groundwater withdrawal of up to 0.120 mgd (30-day average) from the Woodlyn Well (Docket No. 19920501).

18. *Project Sponsor and Facility:* State College Borough Water Authority, Benner Township, Centre County, Pa. Applications for renewal of groundwater withdrawal (30-day averages) of up to 1.584 mgd from Well 17, 0.576 mgd from Well 18, and 1.512 mgd from Well 19 (Docket No. 19930501).

19. *Project Sponsor:* TableTrust Brands LLC. Project Facility: Freebird East, Bethel Township, Lebanon County, Pa. Application for renewal of groundwater withdrawal of up to 0.199 mgd (30-day average) from Well 8 (Docket No. 19990701).

20. *Project Sponsor:* UGI Development Company. Project Facility: Hunlock Creek Energy Center (Susquehanna River), Hunlock Township, Luzerne County, Pa. Applications for renewal of surface water withdrawal of up to 55.050 mgd (peak day) and consumptive use of up to 2.396 mgd (peak day) (Docket No. 20090916).

21. *Project Sponsor and Facility:* Williamsburg Municipal Authority, Catharine Township, Blair County, Pa. Application for renewal of groundwater withdrawal of up to 0.180 mgd (30-day average) from Well 3 (Docket No. 19940702).

22. *Project Sponsor and Facility:* XTO Energy Inc. (West Branch Susquehanna River), Chapman Township, Clinton

County, Pa. Application for renewal of surface water withdrawal of up to 2,000 mgd (peak day) (Docket No. 20190912). *Located in an Environmental Justice area.*

Projects Tabled

1. *Project Sponsor:* New Enterprise Stone & Lime Co., Inc. Project Facility: Roaring Spring Quarry (Halter Creek 2), Taylor Township, Blair County, Pa. Applications for renewal of consumptive use of up to 0.380 mgd (peak day) and surface water withdrawal of up to 0.288 mgd (peak day) (Docket No. 19940705 and Certificate of Registration No. GF-202204215).

2. *Project Sponsor and Facility:* Strasburg Lancaster County Borough Authority, Strasburg Township, Lancaster County, Pa. Application for renewal of groundwater withdrawal of up to 0.275 mgd (30-day average) from the Fisher Well (Docket No. 19890107). *Service area is located in an Environmental Justice area.*

Authority: Public Law 91-575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: September 18, 2024.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2024-21698 Filed 9-25-24; 8:45 am]

BILLING CODE 7040-01-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Denton and Collin Counties, Texas

AGENCY: Federal Highway Administration (FHWA), Department of Transportation.

ACTION: Federal notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: Pursuant to applicable Federal regulations, FHWA, on behalf of TxDOT, is issuing this notice to advise the public that an EIS will be prepared for a proposed transportation project CSJ 0918-46-341, to construct a six-lane freeway primarily on new location connecting Interstate 35 (I-35) in Denton County, Texas with the Dallas North Tollway (DNT) in Collin County, Texas.

FOR FURTHER INFORMATION CONTACT: Mr. Liang Ding, P.E., Project Manager, TxDOT Dallas District, 4777 East Highway 80, Mesquite, Texas 75150; Phone (214) 320-6625; email:

Liang.Ding@txdot.gov. TxDOT's normal business hours are 8:00 a.m.–5:00 p.m. (central time), Monday through Friday.

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable Federal environmental laws for this project are being, or have been, carried out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated December 9, 2019, and executed by FHWA and TxDOT.

The purpose of the proposed action is to address population and travel demand growth and support safe and resilient east-west mobility and connectivity across Denton County. The need for the proposed action is driven by (a) rapid population growth and increasing traffic volumes that are contributing to congestion, (b) higher crash rates along Study Area roadways compared to the statewide average, and (c) limited mobility due to the lack of contiguous east-west arterials.

The proposed six-lane access-controlled freeway with one-way frontage roads on each side would be constructed within an anticipated typical right-of-way footprint 500 feet wide and extend about 23 miles across northern Denton County connecting I-35 to the DNT in Collin County, CSJ 0918-46-341. In addition to the build alternatives, project alternatives to be considered include the No-Build Alternative, transit and other transportation modes, and transportation system management.

In May 2024, Denton County concluded the Denton County Outer Loop Feasibility Study that recommended two general end-to-end alignments for the construction of the proposed freeway connecting I-35 and the DNT. This EIS will evaluate four build alternatives and the No-Build Alternative. The following five segments from the recommended feasibility study alignments combine to form the four build alternatives under consideration:

Segment A connects I-35 on the west along a primarily new location alignment to Farm-to-Market (FM) Road 428 near FM 2153. Segment A follows a section of Rector Rd. from I-35 to Trietsch Rd.

Segment B also connects I-35 on the west on a primarily new location alignment to FM 428 near FM 2153. Segment B follows a portion of Milam Rd. from I-35 to FM 2164.

Segment C is the common segment for all four build alternatives considered, extending along the existing alignment of FM 428 between FM 2153 and Wildcat Rd. which crosses the Elm Fork Trinity River and the Ray Roberts Lake

State Park Greenbelt in the center of the Study Area.

Segment D connects Wildcat Rd. on the west to the DNT on the east in Collin County. Segment D is primarily on new location except where it follows sections of FM 428 between FM 1385 and the DNT.

Segment E also connects Wildcat Rd. on the west to the DNT on the east in Collin County. Segment E is primarily on new location except where it follows sections of Blackjack Rd. and FM 428 between FM 1385 and the DNT.

These segments, when linked end-to-end connecting the logical termini of I-35 and the DNT, result in the Red, Purple, Blue, and Gold Alternatives described below.

The Red Alternative is composed of Segments A, C, and D for a length of about 23.3 miles. The Red Alternative begins at I-35 and Rector Rd. in Denton County and travels east to FM 2164, then curves north and back south to connect to FM 428 near FM 2153. It follows FM 428 over the Elm Fork Trinity River to slightly west of the City of Aubrey where it curves around the north edge of Aubrey crossing US 377, to continue east, then curving south to connect to FM 428/Spring Hill Rd. west of FM 1385, and continues east along the general alignment of FM 428 to connect to the DNT in Collin County. Grade-separated interchanges would be considered at I-35, US 377, the DNT, and other major road crossings.

The Purple Alternative, about 22.7 miles long, is composed of Segments A, C, and E. It begins at I-35 and Rector Rd. in Denton County and travels east to FM 2164, then curves north and back south to connect to existing FM 428 near FM 2153. It follows FM 428 over the Elm Fork Trinity River to slightly west of the City of Aubrey where it curves around the north edge of Aubrey crossing US 377, tying into Blackjack Rd. and following Blackjack Rd. to the east and curving south to cross FM 2931 to follow the general alignment of FM 428/Spring Hill Rd. to the east to connect to the DNT in Collin County. Grade-separated interchanges would be considered at I-35, US 377, the DNT, and other major road crossings.

The Blue Alternative is composed of Segments B, C, and E for a length of about 22.4 miles. The Blue Alternative begins at I-35 and Milam Rd. extending east along Milam Rd. to FM 2164 where it curves north and east to follow Shepard Rd. and then curves south to connect to FM 428 near FM 2153. It follows FM 428 over the Elm Fork Trinity River to slightly west of the City of Aubrey where it curves around the north edge of Aubrey crossing US 377,

tying into Blackjack Rd. and following Blackjack Rd. to the east and curving south to cross FM 2931 to follow the general alignment of FM 428/Spring Hill Rd. to the east to connect to the DNT in Collin County. Grade-separated interchanges would be considered at I-35, US 377, the DNT, and other major road crossings.

The Gold Alternative, about 23.0 miles long, is composed of Segments B, C, and D. It begins at I-35 and Milam Rd. extending east along Milam Rd. to FM 2164 where it curves north and east to follow Shepard Rd. and then curves south to connect to FM 428 near FM 2153. It follows FM 428 over the Elm Fork Trinity River to slightly west of the City of Aubrey where it curves around the north edge of Aubrey crossing US 377, to continue east, then curving south to connect to existing FM 428/Spring Hill Rd. west of FM 1385, and continues east along the general alignment of FM 428 to connect to the DNT in Collin County. Grade-separated interchanges would be considered at I-35, US 377, the DNT, and other major road crossings.

The new location build alternatives share common alignments with the potential to result in wetland and waters of the U.S. impacts, floodplain/floodway encroachment and the need for compensatory storage, encroachment onto Federal conservation easements, the use of public parkland (Section 4(f)), loss of woodlands, conversion of farmland to transportation use, residential and business displacements, impacts to potential hazardous material sites, traffic noise, changes to the visual environment, impacts to historic and archeological resources, and induced growth and cumulative effects.

The proposed action may require issuance of an Individual or Nationwide Permit under section 404 of the Clean Water Act, an individual Section 401 Water Quality Certification, a Section 402/Texas Pollutant Discharge Elimination System Permit, and a Section 408 Permit; conformance with Executive Orders on Environmental Justice (12898), Limited English Proficiency (13166), Wetlands (11990), Floodplain Management (11988), Invasive Species (13112); and compliance with Section 106 of the National Historic Preservation Act, Section 7 of the Endangered Species Act, the Migratory Bird Treaty Act, section 4(f) of the DOT Act (49 U.S.C. 303), section 6(f) of the Land and Water Conservation Act (16 U.S.C. 4601), title VI of the Civil Rights Act, and other applicable Federal and State regulations.

TxDOT anticipates completing the study process for this proposed action by September 2026. The Draft EIS would be issued in February 2026, and the combined Final EIS and Record of Decision (ROD) would be issued in September 2026.

The following entities have been invited to be cooperating agencies for this EIS: U.S. Army Corps of Engineers, Fort Worth District (USACE), Texas Parks and Wildlife Department (TPWD), and the Texas Historical Commission (THC).

The following entities have been invited to be participating agencies for this EIS: Comanche Nation of Oklahoma; Delaware Nation; Federal Aviation Administration; Federal Railroad Administration; Federal Transit Administration, Region 6; Jena Band of Choctaw Indians; Kiowa Tribe; Mescalero Apache Tribe; North Central Texas Council of Governments; North Texas Municipal Water District; North Texas Tollway Authority; Public Utility Commission of Texas; Shawnee Tribe; Texas Commission on Environmental Quality; Texas Department of Housing and Community Affairs; Texas General Land Office; Texas Railroad Commission; Texas State Soil and Water Conservation Board; The Lakes Freshwater District; The Muskogee Nation; Tonkawa Tribe of Oklahoma; Upper Trinity Regional Water District; U.S. Coast Guard; U.S. Department of Agriculture, Natural Resources Conservation Service; U.S. Department of Homeland Security, Federal Emergency Management Agency; U.S. Department of Housing and Urban Development; U.S. Department of the Interior, Fish and Wildlife Service; U.S. Environmental Protection Agency, Region 6; Wichita and Affiliated Tribes; Collin County; City of Aubrey; City of Celina; City of Cross Roads; City of Dallas Water Utilities; City of Denton; City of Frisco; City of Krugerville; City of Pilot Point; and City of Sanger.

TxDOT intends to coordinate throughout the NEPA process with the USACE to enable them to adopt the Draft and Final EIS, or portions thereof, to determine its overall sufficiency in order to identify and substantiate the USACE's Preliminary Least Environmentally Damaging Most Practicable Alternative (LEDPA) and to develop their own ROD to provide the basis for future Division of the Army permit and real estate decisions; the TPWD under the 2021 Memorandum of Understanding for the review and coordination of transportation projects codified under title 43, Texas Administrative Code, part 1, chapter 2, subchapter G, sections 2.201–2.207 and

as an owner and manager of public lands within the Study Area protected by chapter 26 of the Parks and Wildlife Code; and the THC under the Texas Antiquities Code, section 106 of the National Historic Preservation Act, and Section 4(f) of the DOT Act for potential unavoidable impacts to National Register of Historic Places eligible resources.

TxDOT will issue a single Final EIS and ROD document pursuant to 23 U.S.C. 139(n)(2), unless TxDOT determines statutory criteria or practicability considerations preclude the issuance of a combined document.

In accordance with 23 U.S.C. 139, cooperating agencies, participating agencies, and the public will be given an opportunity for continued input on project development. An agency scoping meeting was held with cooperating and participating agencies on September 4, 2024, with comments requested by September 20, 2024. Public scoping meetings are planned for October 29, 2024, in Pilot Point and October 30, 2024, in Denton. The scoping meetings provide an opportunity for the cooperating and participating agencies along with stakeholders and the public to review and comment on the draft coordination plan and schedule, the project purpose and need, the range of alternatives, and methodologies and level of detail for analyzing alternatives. They will also allow all parties an opportunity to provide input on any expected environmental impacts, anticipated permits or other authorizations, and any significant issues that should be analyzed in depth in the EIS. Notices will be published in October 2024 announcing the time and location of each public scoping meeting. In addition to public scoping meetings, other public meetings will be held during the development of the Draft EIS and public hearings will be held after the Draft EIS is prepared. Public notice will be given of the date, time, and location of future meetings and hearings.

The public meetings and hearings will be conducted in English. If you need an interpreter or document translator because English is not your primary language or you have difficulty communicating effectively in English, one will be provided to you. If you have a disability and need assistance, special arrangements can be made to accommodate most needs. If you need interpretation or translation services or you are a person with a disability who requires an accommodation to attend and participate in the public meeting, please contact Madeline Shepherd, Denton County Outer Loop Project

Team, *info@dentoncountyyouterloop.com*, by mail to Burns & McDonnell, ATTN: Denton County Outer Loop, 13737 Noel Road, Suite 700, Dallas, Texas 75240, or at (469) 294-4502 no later than 4 p.m. CT, on October 24, 2024. Please be aware that advance notice is required as some services and accommodations may require time for the Texas Department of Transportation to arrange.

The public is requested to provide comments on alternatives or impacts and on relevant information, studies, or analyses with respect to this proposed project. Comments may be provided in writing to Madeline Shepherd, Denton County Outer Loop Project Team, *info@dentoncountyyouterloop.com* or by mail to Burns & McDonnell, ATTN: Denton County Outer Loop, 13737 Noel Road, Suite 700, Dallas, Texas 75240. Comments must be received by November 29, 2024.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

Authority: 23 CFR 771.123(a).

Michael T. Leary,
Director, Planning and Program Development,
Federal Highway Administration.

[FR Doc. 2024-22011 Filed 9-25-24; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2012-0332; FMCSA-2014-0104; FMCSA-2014-0387; FMCSA-2016-0002; FMCSA-2017-0058; FMCSA-2017-0059; FMCSA-2017-0060; FMCSA-2017-0061; FMCSA-2018-0135; FMCSA-2020-0026; FMCSA-2020-0027; FMCSA-2022-0035]

Qualification of Drivers; Exemption Applications; Hearing

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 23 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these hard of hearing and deaf individuals to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the

dates stated in the discussions below and will expire on the dates provided below. Comments must be received on or before October 28, 2024.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA-2012-0332, Docket No. FMCSA-2014-0104, Docket No. FMCSA-2014-0387, Docket No. FMCSA-2016-0002, Docket No. FMCSA-2017-0058, Docket No. FMCSA-2017-0059, Docket No. FMCSA-2017-0060, Docket No. FMCSA-2017-0061, Docket No. FMCSA-2018-0135, Docket No. FMCSA-2020-0026, Docket No. FMCSA-2020-0027, or Docket No. FMCSA-2022-0035 using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov/, insert the docket number (FMCSA-2012-0332, FMCSA-2014-0104, FMCSA-2014-0387, FMCSA-2016-0002, FMCSA-2017-0058, FMCSA-2017-0059, FMCSA-2017-0060, FMCSA-2017-0061, FMCSA-2018-0135, FMCSA-2020-0026, FMCSA-2020-0027, or FMCSA-2022-0035) in the keyword box and click "Search." Next, sort the results by "Posted (Newer-Older)," choose the first notice listed, and click on the "Comment" button. Follow the online instructions for submitting comments.

- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery:* West Building Ground Floor, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal Holidays.

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

To avoid duplication, please use only one of these four methods. See the "Public Participation" portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001, (202) 366-4001, fmcsamedical@dot.gov. Office hours are 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA-2012-0332, Docket No. FMCSA-2014-0104, Docket No. FMCSA-2014-0387, Docket No. FMCSA-2016-0002, Docket No. FMCSA-2017-0058, Docket No. FMCSA-2017-0059, Docket No. FMCSA-2017-0060, Docket No. FMCSA-2017-0061, Docket No. FMCSA-2018-0135, Docket No. FMCSA-2020-0026, Docket No. FMCSA-2020-0027, or Docket No. FMCSA-2022-0035), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to www.regulations.gov/, insert the docket number (FMCSA-2012-0332, FMCSA-2014-0104, FMCSA-2014-0387, FMCSA-2016-0002, FMCSA-2017-0058, FMCSA-2017-0059, FMCSA-2017-0060, FMCSA-2017-0061, FMCSA-2018-0135, FMCSA-2020-0026, FMCSA-2020-0027, or FMCSA-2022-0035) in the keyword box and click "Search." Next, sort the results by "Posted (Newer-Older)," choose the first notice listed, click the "Comment" button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number (FMCSA-2012-0332, FMCSA-2014-0104, FMCSA-2014-0387, FMCSA-2016-0002, FMCSA-2017-0058, FMCSA-2017-0059, FMCSA-2017-0060, FMCSA-2017-0061, FMCSA-2018-0135, FMCSA-2020-0026, FMCSA-2020-0027, or FMCSA-2022-0035) in the keyword box and click "Search." Next, sort the results by "Posted (Newer-Older)," choose the first

notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. 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 (Federal Docket Management System), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>, the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, (35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 8, 1971), respectively).

The 23 individuals listed in this notice have requested renewal of their

exemptions from the hearing standard in § 391.41(b)(11), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 23 applicants has satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 23 drivers in this notice remain in good standing with the Agency. In addition, for commercial driver's license (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of these drivers for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of October and are discussed below. As of October 3, 2024, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following nine individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Hagop Balian (IL)
Mataio Brown (MS)
Byron Davis (TX)
Eddie Martinez (TX)
Donnie McEntire (GA)
Willie Miller (IA)
Byron Smith (LA)
Brandon Soto (MO)
Michael Tayman (ME)

The drivers were included in docket number FMCSA–2012–0332, FMCSA–2014–0104, FMCSA–2014–0387, FMCSA–2017–0060, FMCSA–2017–0061, FMCSA–2020–0026, FMCSA–2020–0027, or FMCSA–2022–0035. Their exemptions are applicable as of October 3, 2024 and will expire on October 3, 2026.

As of October 13, 2024, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Cory Adkins (FL)
Matthew Albrecht (PA)
Agustin Hernandez (TX)
Jacquelyn Hetherington (OK)
Andrew Hippler (ID)
Jose Ramirez (IL)
Daniel Stroud (UT)
Jason Wynne (TX)

The drivers were included in docket number FMCSA–2016–0002, FMCSA–2017–0058, FMCSA–2017–0059, FMCSA–2017–0061, or FMCSA–2018–0135. Their exemptions are applicable as of October 13, 2024 and will expire on October 13, 2026.

As of October 30, 2024, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following six individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Adrian Almanza (IL)
James Bryan (AR)
William Heath (NC)
Marty Posey (IN)
Anthony Vasquez (TX)
Daniel Zeolla (PA)

The drivers were included in docket number FMCSA–2020–0027. Their exemptions are applicable as of October 30, 2024 and will expire on October 30, 2026.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must report any crashes or accidents as defined in § 390.5T; and (2) report all citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 to FMCSA; and (3) each driver prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements. Each

exemption will be valid for 2 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 23 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the hearing requirement in 391.41(b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024-21990 Filed 9-25-24; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2012-0294; FMCSA-2013-0443; FMCSA-2013-0445; FMCSA-2014-0212; FMCSA-2014-0213; FMCSA-2015-0321; FMCSA-2018-0051; FMCSA-2018-0052; FMCSA-2018-0054; FMCSA-2019-0033; FMCSA-2020-0046; FMCSA-2022-0044]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 15 individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have “no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.” The exemptions enable these individuals who have had one or more seizures and

are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: The exemptions are applicable on October 21, 2024. The exemptions expire on October 21, 2026. Comments must be received on or before October 28, 2024.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA-2012-0294, Docket No. FMCSA-2013-0443, Docket No. FMCSA-2013-0445, Docket No. FMCSA-2014-0212, Docket No. FMCSA-2014-0213, Docket No. FMCSA-2015-0321, Docket No. FMCSA-2018-0051, Docket No. FMCSA-2018-0052, Docket No. FMCSA-2018-0054, Docket No. FMCSA-2019-0033, Docket No. FMCSA-2020-0046, or Docket No. FMCSA-2022-0044 using any of the following methods:

- **Federal eRulemaking Portal:** Go to www.regulations.gov/, insert the docket number (FMCSA-2012-0294, FMCSA-2013-0443, FMCSA-2013-0445, FMCSA-2014-0212, FMCSA-2014-0213, FMCSA-2015-0321, FMCSA-2018-0051, FMCSA-2018-0052, FMCSA-2018-0054, FMCSA-2019-0033, FMCSA-2020-0046, or FMCSA-2022-0044) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click on the “Comment” button. Follow the online instructions for submitting comments.

- **Mail:** Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Washington, DC 20590-0001.

- **Hand Delivery:** West Building Ground Floor, 1200 New Jersey Avenue SE, Washington, DC 20590-0001 between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal Holidays.

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

To avoid duplication, please use only one of these four methods. See the “Public Participation” portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, (202) 366-4001, fmcsamedical@dot.gov. Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA-2012-0294, Docket No. FMCSA-2013-0443, Docket No. FMCSA-2013-0445, Docket No. FMCSA-2014-0212, Docket No. FMCSA-2014-0213, Docket No. FMCSA-2015-0321, Docket No. FMCSA-2018-0051, Docket No. FMCSA-2018-0052, Docket No. FMCSA-2018-0054, Docket No. FMCSA-2019-0033, Docket No. FMCSA-2020-0046, or Docket No. FMCSA-2022-0044), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to www.regulations.gov/, insert the docket number (FMCSA-2012-0294, FMCSA-2013-0443, FMCSA-2013-0445, FMCSA-2014-0212, FMCSA-2014-0213, FMCSA-2015-0321, FMCSA-2018-0051, FMCSA-2018-0052, FMCSA-2018-0054, FMCSA-2019-0033, FMCSA-2020-0046, or FMCSA-2022-0044) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, click the “Comment” button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number (FMCSA-2012-0294, FMCSA-2013-0443, FMCSA-2013-0445, FMCSA-2014-0212, FMCSA-2014-0213, FMCSA-2015-0321, FMCSA-2018-0051, FMCSA-2018-0052, FMCSA-2018-0054, FMCSA-2019-0033, FMCSA-2020-0046, or FMCSA-2022-0044) in the keyword box and

click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. 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 (Federal Docket Management System), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>, the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. However, FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria¹ to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified

to operate a CMV in interstate commerce.

The 15 individuals listed in this notice have requested renewal of their exemptions from the epilepsy and seizure disorders prohibition in § 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 15 applicants has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition. The 15 drivers in this notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period. In addition, for commercial driver's license (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

As of October 21, 2024, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 15 individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Lee Anderson (MA)

Jay Asack (MA)
Peter Bender (MN)
Ronald Blount (GA)
Eric Hilmer (WI)
Lucas Meeker (OH)
Roland Mezger (PA)
Roger Parker (NC)
Nicholas Ramirez (CA)
Michael Ranalli (PA)
Bryan Sheehan (FL)
Matthew Staley (CO)
Joshua Thomas (MN)
Robert Thomas, Jr. (NC)
Peter Thompson (FL)

The drivers were included in docket number FMCSA–2012–0294, FMCSA–2013–0443, FMCSA–2013–0445, FMCSA–2014–0212, FMCSA–2014–0213, FMCSA–2015–0321, FMCSA–2018–0051, FMCSA–2018–0052, FMCSA–2018–0054, FMCSA–2019–0033, FMCSA–2020–0046, or FMCSA–2022–0044. Their exemptions are applicable as of October 21, 2024 and will expire on October 21, 2026.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as defined by § 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based on its evaluation of the 15 exemption applications, FMCSA renews

¹ These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. *Epilepsy*: § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

the exemptions of the aforementioned drivers from the epilepsy and seizure disorders prohibition in § 391.41(b)(8). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024–21999 Filed 9–25–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2024–0098]

Transforming Transportation Advisory Committee; Public Meeting

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of public meeting.

SUMMARY: The Office of the Secretary of Transportation (OST) announces a public meeting of the Transforming Transportation Advisory Committee (TTAC) on Thursday, October 17, 2024. This notice announces the date, time, and location of the meeting, which will be virtually open to the public. The purpose of the TTAC is to provide information, advice, and recommendations to the Secretary on matters relating to transportation innovations.

DATES: This meeting will be held on Thursday, October 17, 2024 from 11:00 a.m. to 3:30 p.m. Eastern Time (ET). A link allowing for live viewing of the meeting will be posted to <https://www.transportation.gov/ttac> ahead of the meeting start time.

ADDRESSES: The TTAC members will be meeting virtually via Zoom. The public may attend the meeting virtually, with information available on the USDOT TTAC website (<https://www.transportation.gov/ttac>) at least one week in advance of the meeting date.

FOR FURTHER INFORMATION CONTACT: TTAC Designated Federal Officer, c/o Ben Levine, Deputy Assistant Secretary for Research and Technology, Office of the Secretary, ttac@dot.gov, (202) 941–6180.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Secretary of Transportation (Secretary) established TTAC as a Federal Advisory Committee in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C.

ch. 10) to provide information, advice, and recommendations to the Secretary on matters relating to transportation innovations. TTAC is tasked with advice and recommendations to the Secretary about needs, objectives, plans, and approaches for transportation innovations.

Description of Duties

TTAC will undertake only tasks assigned to it by the Secretary of Transportation or designee and provide direct, first-hand information, advice, and recommendations by meeting and exchanging ideas on the tasks assigned. In addition, TTAC will respond to ad-hoc informational requests from OST.

II. Agenda

At the meeting, the agenda will cover the following topics:

1. Call to Order, Official Statement of the Designated Federal Officer, Meeting Logistics
2. Opening Remarks
3. Subcommittee Updates
4. Recap of Meeting Progress and Review of Next Steps

III. Public Participation

The meeting will be open to the public via livestream. Members of the public who wish to observe the virtual meeting can access the livestream accessible on the following website: <https://www.transportation.gov/ttac>.

We are committed to providing equal access to this meeting for all participants. Sign language interpretation and live-captioning will be available during the livestream. If you need alternative formats or services because of a disability, such as interpretation or other ancillary aids, or if you require translation into a language other than English, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than Thursday, October 10, 2024.

Members of the public may also submit written materials, questions, and comments to the Committee in advance to the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than Thursday, October 10, 2024.

All advance submissions will be reviewed by the Designated Federal Officer. If approved, advance submissions shall be circulated to the TTAC members for review prior to the meeting. All advance submissions will become part of the official record of the meeting.

Authority: The Committee is a discretionary Committee under the authority of the U.S. Department of

Transportation (DOT), established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. ch. 2.

Issued in Washington, DC, on September 20, 2024.

Benjamin Ross Levine,

Deputy Assistant Secretary for Research and Technology.

[FR Doc. 2024–21980 Filed 9–25–24; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List), based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them. Additionally, OFAC is publishing updates to the identifying information of two persons currently included on the SDN List.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (<https://www.treasury.gov/ofac>).

Notice of OFAC Actions

A. On September 19, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons and entities are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Individual:

1. NIKULIN, Dmitry Yuryevich, ul. Palikha, d. 10, Str. 7, Moscow 127055, Russia; DOB 20 Feb 1975; POB Moscow, Russia; nationality Russia; Gender Male; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Passport 772043761 (Russia) expires 14 Dec 2033; National ID No. 4500136712 (Russia); Vice-President, TSMRBANK, OOO (individual) [DPRK3] [RUSSIA-EO14024] (Linked To: TSMRBANK, OOO).

Designated pursuant to section 2(a)(vii) of Executive Order 13722 of March 15, 2016, “Blocking Property of the Government of North Korea and the Workers’ Party of Korea, and Prohibiting Certain Transactions With Respect to North Korea” (E.O. 13722), for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the Government of North Korea, a person whose property and interests in property are blocked pursuant to E.O. 13722.

Designated pursuant to section 1(a)(iii)(C) of Executive Order 14024 of April 15, 2021, “Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation” (E.O. 14024), as amended by Executive Order 14114 of December 22, 2023, “Taking Additional Steps With Respect to the Russian Federation’s Harmful Activities” (E.O. 14114), for being or having been a leader, official, senior executive officer, or member of the board of directors of TSMRBANK, OOO, a person whose property and interests in property are blocked pursuant to E.O. 14024.

Entities:

1. TSMRBANK, OOO (a.k.a. BANK CENTER FOR INTERNATIONAL SETTLEMENTS LLC; a.k.a. BANK TSENTR MEZHDUNARODNYKH RASCHETOV OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU; a.k.a. LLC TSMRBANK), ul. Palikha, d. 10, Str. 7, Moscow 127055, Russia; Website www.nko-cmr.ru; Email Address cmr@cmrbank.ru; BIK (RU) 044525059; Secondary sanctions risk: Ukraine-/Russia-Related Sanctions Regulations, 31 CFR 589.201 and/or 589.209; alt. Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Transactions Prohibited For Persons Owned or

Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Registration ID 1157700005759 (Russia); Tax ID No. 7750056670 (Russia); Government Gazette Number 45000256 (Russia) [UKRAINE-EO13660] [DPRK3] [RUSSIA-EO14024].

Designated pursuant to section 2(a)(ix) of E.O. 13722 for having attempted to materially assist, sponsor, or provide financial, material, or technological support for, or goods or services to or in support of, the Government of North Korea, a person whose property and interests in property are blocked pursuant to E.O. 13722.

Designated pursuant to section 1(a)(i) of E.O. 14024, as amended, for operating or having operated in the financial services sector of the Russian Federation economy.

2. RUSSIAN FINANCIAL CORPORATION (a.k.a. AO RFK-BANK; a.k.a. BANK ROSSISKAYA FINANSOVAYA KORPORATSIYA AKTSIONERNOE OBSHCHESTVO; a.k.a. RFC-BANK; a.k.a. RUSSIAN FINANCIAL CORPORATION BANK JSC), St. George's Lane, D. 1, p. 1, Moscow 125009, Russia; d. 1 corp, 1 per. Georgievski, Moscow 125009, Russia; SWIFT/BIC RFCBRUMM; BIK (RU) 044525257; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214 [SYRIA] [DPRK3] [RUSSIA-EO14024].

Designated pursuant to section 2(a)(ix) of E.O. 13722 for having attempted to materially assist, sponsor, or provide financial, material, or technological support for, or goods or services to or in support of, the Government of North Korea, a person whose property and interests in property are blocked pursuant to E.O. 13722.

Designated pursuant to section 1(a)(i) of E.O. 14024, as amended, for operating or having operated in the financial services sector of the Russian Federation economy.

3. MRB BANK (Cyrillic: КБ МРБ (ООО)) (a.k.a. INTERNATIONAL SETTLEMENT BANK LLC; a.k.a. MEZHDUNARODNYI RASCHETNYI BANK (Cyrillic: МЕЖДУНАРОДНЫЙ РАСЧЕТНЫЙ БАНК)), Stalin Street 20, Tskhinvali, South Ossetia, Georgia; Website <https://mrb-bank.ru/>; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Organization Established Date 15 May 2015; Target Type Financial Institution; Registration Number 1159800030409 (Russia) [DPRK3] [RUSSIA-EO14024].

Designated pursuant to section 2(a)(ix) of E.O. 13722 for having attempted to materially assist, sponsor, or provide financial, material, or technological support for, or goods or services to or in support of, the Government of North Korea, a person whose property and interests in property are blocked pursuant to E.O. 13722.

Designated pursuant to section 1(a)(i) of E.O. 14024, as amended, for operating or having operated in the financial services sector of the Russian Federation economy.

4. STROYTREYD LLC (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ "СТРОЙТРЕЙД") (a.k.a. STROYTRADE; a.k.a.

STROYTREYD (Cyrillic: ООО "СТРОЙТРЕЙД")), Pomesheh 1/1, D. 32, K. 1, Novoyasenevskiy Avenue, Yasenevo District, Moscow 117463, Russia; Suite 1/1, Apt. 1, Bldg. 32, Novoyasenevskiy Prospekt, Municipal district Yasenevo, Moscow 117463, Russia; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Organization Established Date 17 Oct 2023; Tax ID No. 9728108831 (Russia); Public Registration Number 1237700700665 (Russia) [DPRK3] [RUSSIA-EO14024].

Designated pursuant to section 2(a)(ix) of E.O. 13722 for having attempted to materially assist, sponsor, or provide financial, material, or technological support for, or goods or services to or in support of, the Government of North Korea, a person whose property and interests in property are blocked pursuant to E.O. 13722.

Designated pursuant to section 1(a)(i) of E.O. 14024, as amended, for operating or having operated in the financial services sector of the Russian Federation economy.

5. TIMER BANK, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO TIMER BANK; a.k.a. PUBLICHNOE AKTSIONERNOE OBSHCHESTVO TIMER BANK (Cyrillic: ТИМЕР БАНК ПУБЛИЧНОЕ АКЦИОНЕРНОЕ ОБЩЕСТВО); a.k.a. TIMER BANK CO., LTD; a.k.a. TIMER BANK JOINT-STOCK COMPANY; a.k.a. TIMER BANK PAO (Cyrillic: ТИМЕР БАНК ПАО)), d. 23 str, 2, ul. Bakhrushina, Moscow 115054, Russia; 58, prospekt Ibragimova, Kazan, Tatarstan 420066, Russia; Bldg. 2, St. Bakhrushina, 23, Moscow 115054, Russia; SWIFT/BIC TIMERU2K; Website timerbank.ru; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; alt. Secondary sanctions risk: See Section 11 of Executive Order 14024.; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Organization Established Date 03 Oct 1991; Target Type Financial Institution; Tax ID No. 1653016689 (Russia); Government Gazette Number 09265705 (Russia); Legal Entity Number 2534006KGFLPAAXC1X76; Registration Number 1021600000146 (Russia) [DPRK3] [RUSSIA-EO14024] (Linked To: RUSSIAN FINANCIAL CORPORATION).

Designated pursuant to section 2(a)(viii) of E.O. 13722 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, RUSSIAN FINANCIAL CORPORATION, a person whose property and interests in property are blocked pursuant to E.O. 13722.

Designated pursuant to section 1(a)(vii) of E.O. 14024, as amended, for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, RUSSIAN FINANCIAL CORPORATION, a person whose property and interests in property are blocked pursuant to E.O. 14024.

B. Additionally, on September 19, 2024, OFAC updated the SDN List entries for two entities, whose property and interests in property subject to U.S. jurisdiction continue to be blocked. The listing below reflects the amended entries on the SDN List.

Entities:

—From—

1. TRANS KAPITAL LIMITED LIABILITY COMPANY (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ ТРАНС КАПИТАЛ) (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU TRANS KAPITAL; a.k.a. TRANS KAPITAL LLC (Cyrillic: ООО ТРАНС КАПИТАЛ); a.k.a. TRANS KAPITAL, ООО), Room 1, Building 1, Fire Lane, Noginsk, Borodskiy Urban District, Moscow Oblast 142400, Russia; Building 29, SNT Poltevo Territory, Noginsk, Borodskiy Urban District, Moscow Oblast, Russia; Room 1, 3 Lenin Avenue, Balashikha, Moscow Oblast 143900, Russia; Letter B, Office 10, Plot 68, Proyektnaya Street, Balashikha, Moscow Oblast 143921, Russia; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Tax ID No. 5001101089 (Russia); Government Gazette Number 34892010 (Russia); Business Registration Number 1145001004378 (Russia) issued 06 Nov 2014 [DPRK] (Linked To: GAZARYAN, Rafael Anatolyevich).

—To—

1. TRANS KAPITAL LIMITED LIABILITY COMPANY (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ ТРАНС КАПИТАЛ) (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU TRANS KAPITAL; a.k.a. TRANS KAPITAL LLC (Cyrillic: ООО ТРАНС КАПИТАЛ); a.k.a. TRANS KAPITAL, ООО), Room 1, Building 1, Fire Lane, Noginsk, Bogorodskiy Urban District, Moscow Oblast 142400, Russia; Building 29, SNT Poltevo Territory, Noginsk, Bogorodskiy Urban District, Moscow Oblast, Russia; Room 1, 3 Lenin Avenue, Balashikha, Moscow Oblast 143900, Russia; Letter B, Office 10, Plot 68, Proyektnaya Street, Balashikha, Moscow Oblast 143921, Russia; d. 2 pom. 1, per. Izmailovski, Noginsk, Moscow Region 142400, Russia; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Tax ID No. 5001101089 (Russia); Government Gazette Number 34892010 (Russia); Business Registration Number 1145001004378 (Russia) issued 06 Nov 2014 [DPRK] (Linked To: GAZARYAN, Rafael Anatolyevich).

—From—

2. KOREA KWANGSON BANKING CORP (a.k.a. KKBC), Jungson-dong, Sungri Street, Central District, Pyongyang, Korea, North; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214 [NPWMD].

—To—

2. KOREA KWANGSON BANKING CORP (a.k.a. BORDER TRADE SETTLEMENT BANK; a.k.a. DPRK BORDER TRADE SETTLEMENT BANK; a.k.a. KKBC; a.k.a. "BTSB"), Jungson-dong, Sungri Street, Central District, Pyongyang, Korea, North; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214 [NPWMD].

Authorities: E.O. 13722, 81 FR 14943, 3 CFR, 2016 Comp., p. 446; E.O. 14024, 86 FR 20249, 3 CFR, 2021 Comp., p. 542, as amended by E.O. 14114, 88 FR 89271, 3 CFR, 2023 Comp., p. 721.

Dated: September 19, 2024.

Lisa M. Palluconi,

Acting Director, Office of Foreign Assets Control, U.S. Department of the Treasury.
[FR Doc. 2024-22111 Filed 9-25-24; 8:45 am]

BILLING CODE 4810-AL-C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them. OFAC is additionally updating the entries on the SDN List for one vessel.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global

Targeting, tel.: 202-622-2420; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (<https://ofac.treasury.gov/>).

Notice of OFAC Action

On September 18, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4810-AL-P

Individuals:

1. BAGHLANI, Mahmud (Arabic: محمود بغلانی) (a.k.a. BAGHLANI, Mahmood; a.k.a. BAGHLANI, Mahmoud), Iran; DOB 20 Feb 1979; alt. DOB 20 Mar 1978; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport G10528653 (Iran) expires 10 Jun 2028; alt. Passport K56200674 (Iran) expires 09 Mar 2027; National ID No. 1756178471 (Iran); Birth Certificate Number 114 (Iran) (individual) [IRGC] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(ii)(C) of Executive Order 13553 of September 28, 2010, "Blocking Property of Certain Persons With Respect to Serious Human Rights Abuses by the Government of Iran and Taking Certain Other Actions" (E.O. 13553), 75 FR 60567, October 1, 2010, for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13553.

2. ABDI, Ali (Arabic: علی عبدی) (a.k.a. "ABDI, Mohammad Ali Effatpanah Deh Nuy"), South Khorasan Province, Iran; DOB 29 May 1975; POB Torbat-e Heydariyeh, Razavi Khorasan Province, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0701301643 (Iran) (individual) [IRAN-HR].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 as an official of the Government of Iran or as a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

3. AZADEH, Ahmad Reza (Arabic: احمد رضا آزاده) (a.k.a. AZADEH, Ahmadreza), Khuzestan Province, Iran; DOB 31 May 1976; POB Ramhormoz, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 1910107069 (Iran) (individual) [IRAN-HR].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 as an official of the Government of Iran or as a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of

the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

4. FARSANI, Alireza Babaei (Arabic: علیرضا بابایی فارسانی) (a.k.a. FARESANI, Ali Reza Babai (Arabic: علی رضا بابایی فارسانی)), Isfahan Province, Iran; DOB 05 Apr 1976; POB Farsan, Chaharmahal and Bakhtiari Province, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 4679007958 (Iran) (individual) [IRAN-HR].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 as an official of the Government of Iran or as a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

5. ROSHAN, Gholamreza (Arabic: غلامرضا روشن), Khuzestan Province, Iran; DOB 01 Dec 1978; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 3030118861 (Iran) (individual) [IRAN-HR].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13553 as an official of the Government of Iran or as a person acting on behalf of the Government of Iran (including members of paramilitary organizations) who is responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against persons in Iran or Iranian citizens or residents, or the family members of the foregoing, on or after June 12, 2009, regardless of whether such abuses occurred in Iran.

6. BAZVAND, Mustafa (Arabic: مصطفى بازوند) (a.k.a. BAZVAND, Mostafa), Iran; DOB 21 Sep 1988; POB Rumeshkan, Lorestan Province, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRGC] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(ii)(C) of Executive Order 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13553.

7. BEHESHTI RAD, Saeed (Arabic: سعید بهشتی راد) (a.k.a. BEHESHTIRAD, Saeed; a.k.a. BEHESHTIRAD, Sa'id); DOB 23 Sep 1977; POB Kermanshah, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 3251912062 (Iran) (individual) [IRGC] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(ii)(C) of Executive Order 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13553.

8. KHORRAMDEL, Hamid (Arabic: حميد خرم دل) (a.k.a. KHORRAM DEL, Hamid), Bagh Zahra Mehrgan 9 P 211, Bushehr, Iran; DOB 15 Jul 1973; POB Bushehr, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 3500565093 (Iran) (individual) [IRGC] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(ii)(C) of Executive Order 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13553.

9. SHAHKOUI, Ali Malek (Arabic: علی ملک ساهکونی) (a.k.a. SHAHKOUEI, Ali Jomeh Malak; a.k.a. SHAHKU'I, Ali Malek), Iran; DOB 09 Aug 1987; POB Gorgan, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 2122857447 (Iran) (individual) [IRGC] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(ii)(C) of Executive Order 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13553.

10. PANJAKI, Yahya Hosseini (Arabic: یحیی حسینی پنجکی) (a.k.a. HAMIDI, Seyed Yahya; a.k.a. HAMIDI, Yahya; a.k.a. PANJAKI, Seyed Yahya Hosseiny; a.k.a. PANJAKI, Yahya Husseini), Iran; DOB 23 Jan 1975; POB Karaj, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport T56344199 (Iran) expires 30 Mar 2027 (individual) [IRAN-HR] (Linked To: IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY).

Designated pursuant to section 1(a)(ii)(C) of Executive Order 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY, a person whose property and interests in property are blocked pursuant to E.O. 13553.

11. GHAFFARHADDADI, Javad (Arabic: جواد غفار حدادی), Iran; DOB 23 Sep 1964; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport F57122360 (Iran) expires 15 Jun 2027 (individual) [IRGC] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(ii)(C) of Executive Order 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13553.

12. ZAREIKAJOSANGI, Hamid (Arabic: حمید زارعی کجوسنگی), Iran; DOB 20 May 1987; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport E54687879 (Iran) expires 28 Sep 2026 (individual) [IRGC] [IRAN-HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE).

Designated pursuant to section 1(a)(ii)(C) of Executive Order 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE, a person whose property and interests in property are blocked pursuant to E.O. 13553.

On September 18, 2024, OFAC updated the entry on the SDN List for the following vessel, which continues to be blocked under the relevant sanctions authorities listed below.

1. OHAR (a.k.a. ARTURA) (8RCL2) Crude Oil Tanker Guyana flag; Vessel Registration Identification IMO 9150365; MMSI 750177000 (vessel) [SDGT] (Linked To: CAP TEES SHIPPING CO., LIMITED).

-to-

YORGOS (a.k.a. ARTURA; a.k.a. OHAR) (3E3496) Crude Oil Tanker Sint Maarten flag; Vessel Registration Identification IMO 9150365; MMSI 352002279 (vessel) [SDGT] (Linked To: CAP TEES SHIPPING CO., LIMITED).

Identified as property in which CAP TEES SHIPPING CO., LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended, has an interest.

On September 10, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person are blocked under the relevant sanctions authority listed below.

1. PASHAEV, Dzhamaldin Emirmagomedovich (Cyrillic: ПАШАЕВ, ДЖАМАЛДИН ЭМИРМАГОМЕДОВИЧ) (a.k.a. PASHAEV, Jamaldin), Russia; DOB 10 Mar 1966; POB S. Akhty, Russia; nationality Russia; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport 75310706 (Russia) expires 19 Aug 2026; National ID No. 8210968204 (Russia); Tax ID No. 050401178868 (Russia) (individual) [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) of Executive Order 14024 of April 15, 2021, “Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation,” 86 FR 20249, 3 CFR, 2021 Comp., p. 542 (Apr. 15, 2021) (E.O. 14024) as amended by Executive Order 14114 of December 22, 2023, “Taking Additional Steps With Respect to the Russian Federation's Harmful Activities,” 88 FR 89271, 3 CFR, 2023 Comp., p. 721 (Dec. 22, 2023) (E.O. 14114), for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

Lisa M. Palluconi,
*Acting Director, Office of Foreign Assets
Control, U.S. Department of the Treasury.*
[FR Doc. 2024–21975 Filed 9–25–24; 8:45 am]
BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 5498–SA

AGENCY: Internal Revenue Service (IRS),
Treasury.

ACTION: Notice and request for
comments.

SUMMARY: The Department of the Treasury, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Currently, the IRS is soliciting comments concerning Form 5498–SA; HSA, Archer MSA, or Medicare Advantage MSA Information.

DATES: Written comments should be received on or before November 25, 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 No. 1545–1518 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke, at (202) 317–6009, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at lanita.vandyke@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: HSA, Archer MSA, or Medicare Advantage MSA Information.
OMB Number: 1545–1518.
Form Number: 5498–SA.

Abstract: This form is used to report contributions to a medical savings account as required by Internal Revenue Code section 220(h).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 9,167.

Estimated Time per Response: 10 min.

*Estimated Total Annual Burden
Hours:* 1,559.

The following paragraph applies to all of 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 as long as 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: September 20, 2024.

Molly J. Stasko,

Senior Tax Analyst.

[FR Doc. 2024–22045 Filed 9–25–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

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 information collections, as required by the Paperwork Reduction Act of 1995. The

IRS is soliciting comments concerning preparer penalties-manual signature requirement.

DATES: Written comments should be received on or before November 25, 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 No. 1545–1385 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke, at (202)–317–6009, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at lanita.vandyke@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Preparer Penalties-Manual
Signature Requirement.

OMB Number: 1545–1385.

Regulation Project Numbers: TD 8549.

Abstract: This regulation provides that persons who prepare U.S. Fiduciary income tax returns for compensation may, under certain conditions, satisfy the manual signature requirements by using a facsimile signature. However, they will be required to submit to the IRS a list of the names and identifying numbers of all fiduciary returns which are being filed with a facsimile signature.

Current Actions: There are no changes being made to this existing T.D. at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 20,000.

Estimated Time per Respondent: 1 hour, 12 min.

*Estimated Total Annual Burden
Hours:* 24,000.

The following paragraph applies to all of 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 as long as 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: September 20, 2024.

Molly J. Stasko,
Senior Tax Analyst.

[FR Doc. 2024-22044 Filed 9-25-24; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Plans To Assess the Current Scientific Literature and Historical Detailed Claims Data Regarding Exposure to Per- and Polyfluoroalkyl Substances (PFAS) and Kidney Cancer

AGENCY: Department of Veterans Affairs.

ACTION: Notice of public comment and listening session.

SUMMARY: The Department of Veterans Affairs (VA) announces that it plans to conduct an assessment of the scientific literature and historical claims data to determine whether an association between military environmental exposures and certain medical conditions exists. This scientific assessment will consider the possibility of a relationship between exposure to Per- and polyfluoroalkyl substances (PFAS) and kidney cancer. The population of study will include U.S. service members who may have experienced environmental and/or occupational exposures to PFAS during military service, but additional inclusion criteria will be considered during the scientific assessment. VA is soliciting public comment on the importance of completing this assessment of scientific literature and historical claims data for kidney cancer and other conditions and will also hold a public listening session.

DATES: Written comments must be received on or before December 20, 2024.

Additionally, VA will hold a public listening session virtually via Webex on Tuesday, November 19, 2024. This session will start at 10:00 a.m. Eastern Standard Time (EST) and end at 11:30 a.m. EST and will focus on plans detailed within this **Federal Register** notice. Registration is required.

Individuals/organizations can sign up using the information found in the **SUPPLEMENTARY INFORMATION** section below.

ADDRESSES: Comments must be submitted through www.regulations.gov. Except as provided below, comments received before the close of the comment period will be available at www.regulations.gov for public viewing, inspection, or copying, including any personally identifiable or confidential business information that is included in a comment. We post the comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. VA will not post on [Regulations.gov](http://www.regulations.gov) public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm the individual. VA encourages individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. Any public comment received after the comment period's closing date is considered late and will not be considered in any potential future rulemaking.

FOR FURTHER INFORMATION CONTACT: Dr. Erin Dursa, Ph.D., MPH, Director of Surveillance Military Environmental Exposures, Health Outcomes Military Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, at 202-461-7297.

SUPPLEMENTARY INFORMATION: In accordance with 38 U.S.C. 1172, as created by section 202 of the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022 (also known as the PACT Act), VA is publishing this notice about its planned scientific assessment of the possibility of a relationship between exposure to PFAS and kidney cancer in Veterans.

PFAS are synthetic chemicals found in many products, including but not limited to clothing, adhesives, paper packaging for food, and heat-resistant/

non-stick cookware. They are also a major constituent of fire-fighting foams or aqueous film-forming foams (AFFF) used to extinguish jet fuel fires in military and commercial settings.

A report by the National Academies of Sciences, Engineering, and Medicine (NASEM) reviewed the potential health effects related to PFAS and suggested guidance for clinical follow-up. VA designated a technical working group (TWG) to conduct an assessment pursuant to 38 U.S.C. 1172(c), and the TWG developed recommendations to VA leadership for formal assessment under 38 U.S.C. 1173, pursuant to 38 U.S.C. 1172(d). Members of the TWG were determined based on their subject matter expertise relevant to the NASEM report, Guidance on PFAS Exposure, Testing, and Clinical Follow-Up (2022). The PFAS TWG determined that sufficient evidence exists to justify the evaluation of kidney cancer through the new presumptive decision process for service connection for Veterans exposed to PFAS. This recommendation is based on evidence presented by NASEM and from other scientific authorities, such as International Agency Research on Cancer, Agency for Toxic Substances and Disease Registry, and Environmental Protection Agency.

VA solicits public comment on the importance of completing this assessment of scientific literature and historical claims data for these conditions or others, via written response to this notice or via a virtual listening session for the public to provide feedback. During this listening session, Veterans Health Administration and Veterans Benefits Administration subject matter experts will listen to public feedback and may ask questions but will not be able to share proposals for specific conditions nor address the merits of any comment provided.

Once the conclusions of the assessment have been appropriately reviewed by experts, it may lead to a formal evaluation to inform decisions regarding Veterans' qualifying period of service, such as those who served on active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War, as well as Somalia, Afghanistan, Djibouti, Egypt, Jordan, Lebanon, Syria, Yemen, or Uzbekistan from September 11, 2001, until the present time.

VA is also soliciting public comment, via writing within this notice or via the public listening session, about other conditions that would benefit from review of the possible association, the conditions, and health outcomes related to them.

VA continues to review and assess information about military environmental exposure incidents, emerging scientific evidence regarding toxic substances, and health outcomes in deployed and non-deployed veteran cohorts. Additionally, active epidemiological surveillance and ongoing monitoring of military exposures in collaboration with the Department of Defense are underway. If the assessment of these conditions concludes a possible association between military environmental exposure and an adverse health outcome is present, this may lead to additional research or be subject to a **Federal Register** notice and comment process, as required by section 1172. VA will publish other notices of this type as it reviews other potential adverse health conditions and their possible association with military environmental exposures to provide health care, services, and benefits to Veterans.

As noted, while VA will accept written comments on this notice, the accompanying listening session aims to allow individuals to share their research, input, and comments on certain adverse health conditions associated with military environmental exposure. Participants can also share their recommendations on other conditions that would benefit from review.

- November 19, 2024—Notice of Plans for the Department of Veterans Affairs to Assess the Current Scientific Literature and Historical Claims Data Regarding Exposure to Per- and Polyfluoroalkyl Substances and Cancer. Registration link: <https://www.research.net/r/PFGH8YL>.

Note: This listening session will have closed captioning available via the WebEx platform. The webinar will be recorded and transcribed.

Registration: Individuals interested in attending must register with Webex for

the listening session. We will ask attendees if they want to provide verbal or written feedback during registration so we can coordinate enough time for verbal comments. However, verbal participation is not required to complete registration. If you wish to provide verbal or written feedback during the listening session, please register by November 15, 2024. Individuals who indicate interest in commenting will receive a confirmation message 2 business days before the session. Individuals who wish to submit materials to VA must do so by November 15, 2024.

VA will work to accommodate all individuals who wish to comment verbally. However, VA will prioritize those who registered in advance. The time allotted for individuals to comment verbally will depend on the number of registrations. We will turn off cameras and mute microphones until the presenter's scheduled time to accommodate as many comments as possible. VA will request written submissions if there is not enough time to hear all comments.

Note: During the listening session, VA will not share proposals or address feedback. VA will use suggestions made during this listening session and public comments on VA's plan to improve future evaluations. VA will continue to comply with the requirements of section 1172(a) and ensure appropriate public notice and opportunity for participation.

Special Accommodations: Attendees requiring special accommodations should make their requests to VA no later than November 5, 2024 (2 weeks before the listening session on November 19, 2024) by contacting the point of contact identified in this notice.

After reviewing comments received in response to this notice and the public listening session, VA will conduct the assessment of the specified conditions. VA will then follow the procedures in

38 U.S.C. 1172–1174 for initiating and conducting assessments and formal evaluations. If appropriate, VA will designate a TWG to conduct a scientific assessment pursuant to 38 U.S.C. 1172(c), and the TWG may develop a recommendation for formal evaluations under 38 U.S.C. 1173, pursuant to 38 U.S.C. 1172(d). Once a formal evaluation is commenced, a recommendation with respect to establishing a presumption of service connection must be submitted to the Secretary within 120 days, in accordance with 38 U.S.C. 1173(d). And within 160 days of receiving the recommendation with respect to establishing a presumption of service connection, the Secretary must determine whether a presumption is warranted in accordance with 38 U.S.C. 1174(a). This may include initiating rulemaking to establish new presumptions for some or all the conditions formally evaluated and/or publishing notice in the **Federal Register** of any determination that a presumption or presumptions are unwarranted for some or all of the conditions that were the subject of the scientific assessment.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on September 16, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2024–22031 Filed 9–25–24; 8:45 am]

BILLING CODE 8320–01–P



FEDERAL REGISTER

Vol. 89

Thursday,

No. 187

September 26, 2024

Part II

Department of Defense

Defense Acquisition Regulations Systems

48 CFR Parts 204, 212, 247, 252

Defense Federal Acquisition Regulation Supplement: Modification of
Notification of Intent To Transport Supplies by Sea (DFARS Case 2020–
D026); Final Rule

DEPARTMENT OF DEFENSE**Defense Acquisition Regulations System****48 CFR Parts 204, 212, 247, and 252**

[Docket DARS–2024–0007]

RIN 0750–AL12

Defense Federal Acquisition Regulation Supplement: Modification of Notification of Intent To Transport Supplies by Sea (DFARS Case 2020–D026)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to remove a DFARS solicitation provision and modify the text of an existing DFARS contract clause to include the operative text of that DFARS provision.

DATES: Effective October 1, 2024.

FOR FURTHER INFORMATION CONTACT: David Johnson, telephone 202–913–5764.

SUPPLEMENTARY INFORMATION:**I. Background**

DoD published a proposed rule in the **Federal Register** at 89 FR 20924 on March 26, 2024, to revise the DFARS to remove the solicitation provision at DFARS 252.247–7022, Representation of Extent of Transportation By Sea, and to revise the contract clause at DFARS 252.247–7023, Transportation of Supplies by Sea, accordingly, to effect the purpose of the provision using only the clause. Two respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

There are no changes from the proposed rule.

B. Analysis of Public Comments

Comment: The respondents expressed support for the rule.

Response: DoD acknowledges the respondents' support.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This final rule removes the provision at DFARS 252.247–7022, along with its prescription at DFARS 247.574(a), and amends the clause at DFARS 252.247–7032 accordingly to include the substance of the provision. However, this final rule does not impose any new requirements on contracts at or below the SAT, for commercial products including COTS items, or for commercial services. The clause will continue to apply to acquisitions at or below the SAT, to acquisitions of commercial products including COTS items, and to acquisitions of commercial services.

IV. Expected Impact of the Rule

This change is expected to streamline instructions to contractors regarding notifications of transportation of supplies by sea. Presently, DFARS provision 252.247–7022 is included in nearly all solicitations and DFARS clause 252.247–7023 is included in nearly all contracts. By effectively combining the provision and the clause, this rule will reduce the number of provisions required to be used in solicitations and the number of representations offerors must provide, while still maintaining the effect of DFARS provision 252.247–7022. Therefore, this rule is expected to reduce administrative burden on contractors, including small businesses.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of

Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VII. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

DoD is amending the DFARS to remove a solicitation provision and accordingly to modify the text of an existing DFARS contract clause to include the operative text of that DFARS provision. The objective of this rule is to streamline the instructions to contractors pertaining to the transportation of supplies by sea.

Public comments received in response to the proposed rule raised no issues regarding the initial regulatory flexibility analysis.

This rule will likely affect small entities that will be awarded contract actions that include DFARS clause 252.247–7023, Transportation of Supplies by Sea. Data was obtained from the Procurement Business Intelligence Service for all contracts and modifications that include DFARS clause 252.247–7023 for fiscal years 2020 through 2022. DoD awarded on average 642,310 contract actions per year that included DFARS clause 252.247–7023 to 30,680 unique entities, of which approximately 359,315 contract awards (56 percent) were made to 21,070 unique small entities (69 percent).

The rule does not impose any new reporting, recordkeeping, or compliance requirements.

There are no known significant alternatives that would accomplish the objectives of the rule.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies to this rule. However, these changes to the DFARS do not impose additional information collection requirements to the paperwork burden previously approved by the Office of Management and Budget (OMB) under OMB Control Number 0704–0245, entitled Defense Federal Acquisition Regulation Supplement (DFARS) Part 247, Transportation and Related Clauses.

List of Subjects in 48 CFR Parts 204, 212, 247, and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System amends 48 CFR parts 204, 212, 247, and 252 as follows:

■ 1. The authority citation for parts 204, 212, 247, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 204—ADMINISTRATIVE AND INFORMATION MATTERS**204.1202 [Amended]**

■ 2. Amend section 204.1202 by removing paragraph (2)(xv).

PART 212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 3. Amend section 212.301 by revising paragraph (f)(xxi) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

(f) * * *

(xxi) *Part 247—Transportation.* (A) Use the clause at 252.247–7003, Pass-Through of Motor Carrier Fuel Surcharge Adjustment to the Cost Bearer, as prescribed in 247.207, to comply with section 884 of Public Law 110–417.

(B) Use the basic or one of the alternates of the clause at 252.247–7023, Transportation of Supplies by Sea, as prescribed in 247.574(a), to comply with the Cargo Preference Act of 1904 (10 U.S.C. 2631(a)).

(1) Use the basic clause as prescribed in 247.574(a)(1).

(2) Use the alternate I clause as prescribed in 247.574(a)(2).

(3) Use the alternate II clause as prescribed in 247.574(a)(3).

(C) Use the clause 252.247–7025, Reflagging or Repair Work, as prescribed in 247.574(b), to comply with 10 U.S.C. 2631(b).

(D) Use the provision at 252.247–7026, Evaluation Preference for Use of Domestic Shipyards—Applicable to Acquisition of Carriage by Vessel for DoD Cargo in the Coastwise or Noncontiguous Trade, as prescribed in 247.574(c), to comply with section 1017 of Public Law 109–364.

(E) Use the clause at 252.247–7027, Riding Gang Member Requirements, as

prescribed in 247.574(d), to comply with section 3504 of the National Defense Authorization Act for Fiscal Year 2009 (Pub. L. 110–417).

(F) Use the clause at 252.247–7028, Application for U.S. Government Shipping Documentation/Instructions, as prescribed in 247.207.

PART 247—TRANSPORTATION**247.574 [Amended]**

■ 4. Amend section 247.574—

■ a. By removing paragraph (a);

■ b. By redesignating paragraphs (b) through (e) as paragraphs (a) through (d);

■ c. In newly redesignated paragraph (a) introductory text by removing “all”; and

■ d. In newly redesignated paragraph (d) by removing “under chapter 121 of title 46 U.S.C.” and adding “46 U.S.C. chapter 121.” in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES**252.204–7007 [Amended]**

■ 5. Amend section 252.204–7007—

■ a. By removing the provision date of “NOV 2023” and adding “OCT 2024” in its place; and

■ b. By removing paragraph (d)(1)(viii).

252.247–7022 [Removed and Reserved]

■ 6. Remove and reserve section 252.247–7022.

■ 7. Amend section 252.247–7023—

■ a. By revising the introductory text and the clause date;

■ b. By redesignating paragraphs (b) through (i) as paragraphs (c) through (j);

■ c. By adding a new paragraph (b);

■ d. By revising newly redesignated paragraphs (e)(2), (f) introductory text, and (i);

■ e. In newly redesignated paragraph (j) introductory text by removing “(b)(2)” and adding “(c)(2)” in its place;

■ f. In newly redesignated paragraph (j)(1) by removing “paragraph (i)” and adding “paragraph (j)” in its place;

■ g. In newly redesignated paragraph (j)(2) by removing “paragraphs (a) through (e)” and “paragraph (i)” and adding “paragraphs (a) through (f)” and “paragraph (j)” in their places, respectively;

■ h. In Alternate I—

■ i. By revising the introductory text and the clause date;

■ ii. By redesignating paragraphs (b) through (i) as paragraphs (c) through (j);

■ iii. By adding a new paragraph (b);

■ iv. By revising newly redesignated paragraphs (e)(2), (f) introductory text, and (i);

■ v. In newly redesignated paragraph (j) introductory text by removing “(b)(2)” and adding “(c)(2)” in its place;

■ vi. In newly redesignated paragraph (j)(1) by removing “paragraph (i)” and adding “paragraph (j)” in its place;

■ vii. In the newly redesignated paragraph (j)(2) by removing “paragraphs (a) through (e)” and “paragraph (i)” and adding “paragraphs (a) through (f)” and “paragraph (j)” in their places, respectively; and

■ viii. By adding “(End of clause)” after newly redesignated paragraph (j)(2); and

■ i. In Alternate II—

■ i. By revising the introductory text and the clause date;

■ ii. By redesignating paragraphs (b) through (i) as paragraphs (c) through (j);

■ iii. By adding a new paragraph (b);

■ iv. By revising newly redesignated paragraphs (e)(2), (f) introductory text, and (i);

■ v. In newly redesignated paragraph (j) introductory text by removing “(b)(2)” and adding “(c)(2)” in its place;

■ vi. In newly redesignated paragraph (j)(1) by removing “paragraph (i)” and adding “paragraph (j)” in its place;

■ vii. In newly redesignated paragraph (j)(2) by removing “paragraphs (a) through (e)” and “paragraph (i)” and adding “paragraphs (a) through (f)” and “paragraph (j)” in their places, respectively; and

■ viii. By adding “(End of clause)” after newly redesignated paragraph (j)(2).

The revisions and additions read as follows:

252.247–7023 Transportation of Supplies by Sea.

As prescribed in 247.574(a) and (a)(1), use the following basic clause:

Transportation of Supplies by Sea—Basic (OCT 2024)

* * * * *

(b) If the transportation of supplies by sea is anticipated under this contract, the Contractor shall—

(1) Notify the Contracting Officer and Maritime Administration (MARAD) at *Cargo.Marad@dot.gov*—

(i) Within 3 business days after contract award; or

(ii) Immediately prior to the shipment departure date necessary to meet delivery schedules, whichever is earlier; and

(2) Include in the notification—

(i) A statement of the Contractor’s intent to transport supplies by sea;

(ii) The contract number; and

(iii) The task-order or delivery-order number, when applicable.

* * * * *

(e) * * *

(2) Required shipping date(s) and required delivery date(s);

* * * * *

(f) The Contractor shall, within 30 days after each shipment covered by this clause, provide the Contracting Officer and MARAD at *Cargo.Marad@dot.gov*, Attention: Military Team, one copy of the rated on board vessel operating carrier's ocean bill of lading, which shall contain the following information:

* * * * *

(i) If the Contractor did not anticipate transporting any supplies by sea at the time of contract award and, therefore, did not provide the notification required by paragraph (b) of this clause, but prior to shipment of supplies, the Contractor learns that supplies will be transported by sea, the Contractor shall—

(1) Provide the notification required by paragraph (b) of this clause to the Contracting Officer and MARAD as soon as it is known that supplies will be transported by sea; and

(2) Comply with all the terms and conditions of this clause.

* * * * *

Alternate I. As prescribed in 247.574(a) and (a)(2), use the following clause, which uses a different paragraph (c) than the basic clause:

**Transportation of Supplies by Sea—
Alternate I (OCT 2024)**

* * * * *

(b) If the transportation of supplies by sea is anticipated under this contract, the Contractor shall—

(1) Notify the Contracting Officer and Maritime Administration (MARAD) at *Cargo.Marad@dot.gov*—

(i) Within 3 business days after contract award; or

(ii) Immediately prior to the shipment departure date necessary to meet delivery schedules, whichever is earlier; and

(2) Include in the notification—

(i) A statement of the Contractor's intent to transport supplies by sea;

(ii) The contract number; and

(iii) The task-order or delivery-order number, when applicable.

* * * * *

(e) * * *

(2) Required shipping date(s) and required delivery date(s);

* * * * *

(f) The Contractor shall, within 30 days after each shipment covered by this clause, provide the Contracting Officer and MARAD at *Cargo.Marad@dot.gov*, Attention: Military Team, one copy of the rated on board vessel operating carrier's ocean bill of lading,

which shall contain the following information:

* * * * *

(i) If the Contractor did not anticipate transporting any supplies by sea at the time of contract award and, therefore, did not provide the notification required by paragraph (b) of this clause, but prior to shipment of the supplies, the Contractor learns that supplies will be transported by sea, the Contractor shall—

(1) Provide the notification required by paragraph (b) of this clause to the Contracting Officer and MARAD as soon as it is known that supplies will be transported by sea; and

(2) Comply with all the terms and conditions of this clause.

* * * * *

Alternate II. As prescribed in 247.574(a) and (a)(3), use the following clause, which uses a different paragraph (c) than the basic clause:

**Transportation of Supplies by Sea—
Alternate II (OCT 2024)**

* * * * *

(b) If the transportation of supplies by sea is anticipated under this contract, the Contractor shall—

(1) Notify the Contracting Officer and Maritime Administration (MARAD) at *Cargo.Marad@dot.gov*—

(i) Within 3 business days after contract award; or

(ii) Immediately prior to the shipment departure date necessary to meet delivery schedules, whichever is earlier; and

(2) Include in the notification—

(i) A statement of the Contractor's intent to transport supplies by sea;

(ii) The contract number; and

(iii) The task-order or delivery-order number, when applicable.

* * * * *

(e) * * *

(2) Required shipping date(s) and required delivery date(s);

* * * * *

(f) The Contractor shall, within 30 days after each shipment covered by this clause, provide the Contracting Officer and MARAD at *Cargo.Marad@dot.gov*, Attention: Military Team, one copy of the rated on board vessel operating carrier's ocean bill of lading, which shall contain the following information:

* * * * *

(i) If the Contractor did not anticipate transporting any supplies by sea at the time of contract award, and, therefore, did not provide the notification required by paragraph (b) of this clause, but prior to shipment of the supplies, the Contractor learns after the award of the

contract that supplies will be transported by sea, the Contractor shall—

(1) Provide the notification required by paragraph (b) of this clause to the Contracting Officer and MARAD as soon as it is known that supplies will be transported by sea; and

(2) Comply with all the terms and conditions of this clause.

* * * * *

■ 8. Amend section 252.247–7025—

■ a. By revising the section heading; and

■ b. In the introductory text by removing “247.574(c)” and adding “247.574(b)” in its place.

The revision reads as follows:

252.247–7025 Reflagging or Repair Work.

* * * * *

252.247–7026 [Amended]

■ 9. Amend section 252.247–7026 in the introductory text by removing “247.574(d)” and adding “247.574(c)” in its place.

■ 10. Amend section 252.247–7027—

■ a. By revising the section heading; and

■ b. In the introductory text by removing “247.574(e)” and adding “247.574(d)” in its place.

The revision reads as follows:

252.247–7027 Riding Gang Member Requirements.

* * * * *

[FR Doc. 2024–21091 Filed 9–25–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 242, 247, and 252

[Docket DARS–2024–0013]

RIN 0750–AL38

Defense Federal Acquisition Regulation Supplement: Preference for United States Vessels in Transporting Supplies By Sea (DFARS Case 2021–D020)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 intended to increase compliance with military cargo preference requirements.

DATES: Effective October 1, 2024.

FOR FURTHER INFORMATION CONTACT: David Johnson, telephone 202–913–5764.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 89 FR 31681 on April 25, 2024, to implement section 1024 of the William M. (Mac) Thornberry National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Pub. L. 116–283). Section 1024 amends 10 U.S.C. 2631 to, among other things, clarify circumstances in which DoD may seek a waiver from the basic requirement for DoD supplies to be transported by seas in either vessels belonging to the United States or vessels of the United States. One respondent submitted a public comment in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comment in the development of the final rule. A discussion of the comment is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

There are no changes from the proposed rule resulting from the public comment.

B. Analysis of Public Comments

Comment: The respondent suggested the rule should be changed to include a certification requirement in paragraph (f) of the clause at DFARS 252.242–7023, including alternates, in place of a representation. The respondent further suggested the clause at DFARS 252.247–7025 should similarly include a certification requirement. The respondent expressed that these changes would help ensure full compliance with U.S.-flag vessel preference requirements.

Response: As expressed at DFARS 201.107, 41 U.S.C. 1304 prohibits new certification requirements in the DFARS unless either the certification is specifically imposed by statute or an approved justification exists for the certification. Neither condition is met in this case. Therefore, DoD declines the respondent's suggestion to add certification requirements to the clauses at DFARS 252.242–7023 and 252.247–7025.

C. Other Changes

Two changes are made to the final rule. First, the final rule removes the definition of “foreign shipyard” from DFARS 247.501, because that definition

is not used in subpart 247.5. Secondly, the final rule removes the change included in the proposed rule to the definition of “foreign shipyard” in the solicitation provision at DFARS 252.247–7026, because this change created incongruity with the existing definition of “U.S. shipyard” in the provision.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This final rule amends the clauses at DFARS 252.247–7023, including alternates, 252.247–7025, and the provision at 252.247–7026. However, this final rule does not impose any new requirements on contracts at or below the SAT, for commercial products including COTS items, or for commercial services. The clauses and the provision will continue to apply to acquisitions at or below the SAT, to acquisitions of commercial products including COTS items, and to acquisitions of commercial services.

IV. Expected Impact of the Rule

This rule is intended to increase compliance with military cargo preference requirements, as amended under this rule in accordance with section 1024 of the NDAA for FY 2021. These changes are largely clarifying in nature, including clarification of operational requirements internal to DoD. Therefore, this rule is not expected to have a significant impact on the public.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or

final rule with the form, Submission of Federal Rules Under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VII. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

DoD is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement section 1024 of the William M. (Mac) Thornberry National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021. Section 1024 modifies 10 U.S.C. 2631 to add a requirement to ensure contractor compliance with 10 U.S.C. 2631 and otherwise updates the listed circumstances in which DoD may waive the requirement that DoD supplies be transported by sea in vessels belonging to the United States or vessels of the United States. It also modifies the requirement for reflagging or repair work in the United States for vessels used under time-charter contracts.

The public comment raised no issue in response to the initial regulatory flexibility analysis.

This rule will apply to small entities that have contracts that include DFARS clauses 252.247–7023, Transportation of Supplies by Sea, and 252.247–7025, Reflagging or Repair Work. DoD obtained data from the Procurement Business Intelligence Service for all contracts and modifications that include DFARS clauses 252.247–7023 and 252.247–7025 for fiscal years 2020 through 2022. DoD awarded on average 649,016 contract actions per year that included either DFARS clause 252.247–7023 or 252.247–7025, or both, to 31,665 unique entities, of which approximately 363,260 contract awards (56 percent) were made to 21,737 unique small entities (69 percent).

This rule does not impose any new reporting, recordkeeping, or other compliance requirements.

There are no known alternatives that would accomplish the stated objectives of the applicable statute.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies to this final rule. However, these changes to the DFARS do not impose additional

information collection requirements to the paperwork burden previously approved by the Office of Management and Budget (OMB) under OMB Control Number 0704–0245, titled: Defense Federal Acquisition Regulation Supplement (DFARS) Part 247, Transportation and Related Clauses.

List of Subjects in 48 CFR Parts 242, 247, and 252

Government procurement.

Jennifer D. Johnson,
Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System amends 48 CFR parts 242, 247, and 252 as follows:

■ 1. The authority citation for parts 242, 247, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 242—CONTRACT ADMINISTRATION AND AUDIT SERVICES

■ 2. Amend section 242.1502—

■ a. In paragraph (g)(i) by removing the word “and” at the end of the paragraph;

■ b. In paragraph (g)(ii) by removing the period at the end of the paragraph and adding “; and” in its place; and

■ c. By adding paragraph (g)(iii).

The addition reads as follows:

242.1502 Policy.

(g) * * *

(iii) In accordance with 10 U.S.C. 2631(d), shall include information on contractor compliance with requirements of the clause at 252.247–7023, Transportation of Supplies by Sea (see 10 U.S.C. 2631(a), (b), and (c)).

PART 247—TRANSPORTATION

■ 3. Amend section 247.570—

■ a. By revising paragraph (a)(1);

■ b. In paragraph (a)(2):

■ i. By removing “(Pub. L. 109–364)” and adding “(Pub. L. 109–364) (10 U.S.C. 2631 note)” in its place; and

■ ii. By removing the word “and” at the end of the paragraph;

■ c. In paragraph (a)(3) by removing “(Pub. L. 110–417)” and “chapter 121, title 46 U.S.C.” and adding “(Pub. L. 110–417) (10 U.S.C. chapter 257 note)”

and “46 U.S.C. chapter 121; and” in their places, respectively;

■ d. By adding paragraph (a)(4);

■ e. In paragraph (b) by removing “46 U.S.C. 1241(b)” and adding “46 U.S.C. chapter 553” in its place; and

■ f. By revising paragraph (c).

The revisions and addition read as follows:

247.570 Scope.

* * * * *

(a) * * *

(1) The Military Cargo Preference Act of 1904 (“the 1904 Act”), 10 U.S.C. 2631, which applies to the ocean transportation of cargo owned by, destined for use by, or otherwise transported by DoD;

* * * * *

(4) Section 1024 of the National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283), which updates the listed circumstances where DoD may waive the requirement that DoD supplies be transported by sea in vessels belonging to the United States or vessels of the United States, and it modifies the requirement for reflagging or repair work in the United States for vessels used under time-charter contracts.

* * * * *

(c) Does not implement—

(1) Section 27 of the Merchant Marine Act, 1920 (46 U.S.C. chapters 121 and 552), commonly known as the “Jones Act,” for the application of coastwise trade; or

(2) Waivers thereof pursuant to 46 U.S.C. 501.

■ 4. Revise section 247.571 to read as follows:

247.571 Definitions.

As used in this subpart—

Corrective and preventive maintenance or repair means—

(1) Maintenance or repair actions performed as a result of a failure in order to return or restore equipment to acceptable performance levels; and

(2) Scheduled maintenance or repair actions to prevent or discover functional failures.

Covered vessel means a vessel—

(1) Owned, operated, or controlled by the offeror; and

(2) Qualified to engage in the carriage of cargo in the coastwise or noncontiguous trade under 46 U.S.C. 12112 and 50501 and 46 U.S.C. chapter 551.

Foreign-flag vessel means any vessel that is not a U.S.-flag vessel.

Ocean transportation means any water-borne transportation aboard a ship, vessel, boat, barge, ferry, or the like outside the internal waters of the United States (as defined in 33 CFR 2.24).

Overhaul, repair, and maintenance work means work requiring a shipyard period greater than or equal to 5 calendar days.

Reflagging or repair work means work performed on a vessel—

(1) To enable the vessel to meet applicable standards to become a vessel of the United States; or

(2) To convert the vessel to a more useful military configuration.

Supplies means supplies that are clearly identifiable for eventual use by or owned by DoD at the time of transportation by sea, or are otherwise transported by DoD, regardless of ownership or use by DoD. An item is clearly identifiable for eventual use by DoD if, for example, the contract documentation contains a reference to a DoD contract number or a military destination.

U.S.-flag vessel means either a vessel belonging to the United States or a vessel of the United States as that term is defined in 46 U.S.C. 116.

■ 5. Revise section 247.572 to read as follows:

247.572 Policy.

(a) In accordance with 10 U.S.C.

2631(a), DoD contractors shall transport supplies exclusively on U.S.-flag vessels. In accordance with 10 U.S.C. 2631(b), DoD (see 247.573(a)) may waive this requirement when a U.S.-flag vessel—

(1) Is not available at a fair and reasonable rate for commercial vessels of the United States; or

(2) Is not otherwise available.

(b) Contracts must provide for the use of vessels belonging to the United States when security classifications prohibit the use of other than vessels belonging to the United States.

(c) In accordance with 10 U.S.C.

2631(c)—

(1) Any vessel used under a time charter contract for the transportation of supplies under this section shall have the following work performed in the United States or its outlying areas:

(i) Reflagging or repair work, if the reflagging or repair work is performed—

(A) On a vessel for which the contractor submitted an offer in response to the solicitation for the contract; and

(B) Prior to acceptance of the vessel by the Government.

(ii) Corrective and preventive maintenance or repair work for the duration of the contract, to the greatest extent practicable.

(2) The Secretary of Defense may waive this requirement if the Secretary determines that such waiver is critical to the national security of the United States. In accordance with 10 U.S.C. 2631(c)(2), DoD shall immediately submit, in writing, a notice to the congressional committees listed at 10 U.S.C. 2631(e) of such a waiver and the reason for the waiver.

(d) In accordance with section 1017 of the National Defense Authorization Act for Fiscal Year 2007 (Pub. L. 109–364), when obtaining carriage requiring a covered vessel, the contracting officer shall consider the extent to which offerors have had overhaul, repair, and maintenance work for covered vessels performed in shipyards located in the United States or Guam.

(e) In accordance with section 3504 of the National Defense Authorization Act for Fiscal Year 2009 (Pub. L. 110–417), DoD may not award, renew or extend, or exercise an option under a charter of, or contract for carriage of cargo by, a U.S.-flag vessel documented under 46 U.S.C. chapter 121, unless the contract contains the clause at 252.247–7027.

■ 6. Amend section 247.573—

■ a. By revising paragraphs (a) and (b)(3);

■ b. In paragraph (b)(4) by removing “Procedures are provided at” and adding “Follow the procedures at” in its place; and

■ c. By adding paragraph (b)(5).

The revisions and addition read as follows:

247.573 General.

(a) *Delegated authority.* Pursuant to 10 U.S.C. 2631(b)(2), the Secretary of Defense has delegated (see PGI 247.573) the authority to make determinations either that a U.S.-flag vessel is not available at a fair and reasonable rate for commercial vessels of the United States or is otherwise not available to—

(1) The Commander, United States Transportation Command; and

(2) The Secretary of the Navy.

(b) * * *

(3) See PGI 247.573(b)(3) for agency and department procedures relating to annual reporting requirements of waivers granted for nonavailability of U.S.-flag vessels.

* * * * *

(5)(i) In accordance with 10 U.S.C. 2631(d), contracting officers shall exercise appropriate contractual rights and remedies against contractors who fail to comply. Such remedies may include the determination that a contractor is ineligible for award of future contracts, termination of an existing contract, or suspension or debarment of the contractor. Also see 242.1502 regarding assessments of the contractor’s past performance.

(ii) In the event of a contractor’s unauthorized use of foreign-flag vessels in the performance of a contract, the contracting officer is authorized to consider an equitable adjustment.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 7. Amend section 252.247–7023—

■ a. By revising paragraphs (a) and (d);

■ b. In paragraph (e) introductory text by revising the second sentence;

■ c. By revising paragraph (e)(7);

■ d. In paragraph (f)(10) by removing “the steamship company” and adding “the carrier” in its place;

■ e. In paragraph (g)(3) by removing “had the written consent of the Contracting Officer” and adding “had received a prior-approved waiver for U.S.-flag vessels” in its place;

■ f. In paragraph (g)(4) by removing “of the Contracting Officer” and adding “of DoD” in its place;

■ g. In Alternate I—

■ i. By revising paragraphs (a) and (d);

■ ii. In paragraph (e) introductory text by revising the second sentence;

■ iii. By revising paragraph (e)(7);

■ iv. In paragraph (f)(10) by removing “steamship company” and adding “the carrier” in its place;

■ v. In paragraph (g)(3) by removing “had the written consent of the Contracting Officer” and adding “had received a prior-approved waiver for U.S.-flag vessels” in its place; and

■ vi. In paragraph (g)(4) by removing “of the Contracting Officer” and adding “of DoD” in its place; and

■ h. In Alternate II—

■ i. By revising paragraphs (a) and (d);

■ ii. In paragraph (e) introductory text by revising the second sentence;

■ iii. By revising paragraph (e)(7);

■ iv. In paragraph (f)(10) by removing “steamship company” and adding “the carrier” in its place;

■ v. In paragraph (g)(3) by removing

“had the written consent of the Contracting Officer” and adding “had received a prior-approved waiver for U.S.-flag vessels” in its place; and

■ vi. In paragraph (g)(4) by removing “of the Contracting Officer” and adding “of DoD” in its place.

The revisions read as follows:

252.247–7023 Transportation of Supplies by Sea.

* * * * *

(a) *Definitions.* As used in this clause—

Foreign-flag vessel means any vessel that is not a U.S.-flag vessel.

Ocean transportation means any water-borne transportation aboard a ship, vessel, boat, barge, ferry, or the like outside the internal waters of the United States as defined in 33 CFR 2.24.

Subcontractor means a supplier, materialman, distributor, or vendor at any level below the prime contractor

whose contractual obligation to perform results from, or is conditioned upon, award of the prime contract and who is performing any part of the work or other requirement of the prime contract.

Supplies means supplies that are clearly identifiable for eventual use by or owned by DoD at the time of transportation by sea, or are otherwise transported by DoD, regardless of ownership or use by DoD. An item is clearly identifiable for eventual use by DoD if, for example, the contract documentation contains a reference to a DoD contract number or a military destination.

U.S.-flag vessel means either a vessel belonging to the United States or a vessel of the United States as that term is defined in 46 U.S.C. 116.

* * * * *

(d) The Contractor and its subcontractors may request, via the Contracting Officer, a waiver of the requirement to use a U.S.-flag vessel, or identification of any available U.S.-flag vessels, if the Contractor or a subcontractor sufficiently explains that—

(1) U.S.-flag vessels are not available at a fair and reasonable rate for commercial vessels of the United States; or

(2) U.S.-flag vessels are otherwise not available.

(e) * * * The Contracting Officer will process requests submitted after such date(s) as expeditiously as possible, however, if a DoD waiver is not approved prior to the shipper’s sailing date, this will not of itself constitute a compensable delay under this or any other clause of this contract. * * *

* * * * *

(7) A documented description of current, diligent efforts made to secure U.S.-flag vessels, including points of contact (with names and telephone numbers) with at least two U.S.-flag carriers contacted. Copies of quotes will suffice for this purpose. Copies of telephone notes, emails, and other relevant communications will otherwise be considered for this purpose.

* * * * *

Alternate I. * * *

(a) *Definitions.* As used in this clause—

Foreign-flag vessel means any vessel that is not a U.S.-flag vessel.

Ocean transportation means any water-borne transportation aboard a ship, vessel, boat, barge, ferry, or the like outside the internal waters of the United States as defined in 33 CFR 2.24.

Subcontractor means a supplier, materialman, distributor, or vendor at any level below the prime contractor

whose contractual obligation to perform results from, or is conditioned upon, award of the prime contract and who is performing any part of the work or other requirement of the prime contract.

Supplies means supplies that are clearly identifiable for eventual use by or owned by DoD at the time of transportation by sea, or are otherwise transported by DoD, regardless of ownership or use by DoD. An item is clearly identifiable for eventual use by DoD if, for example, the contract documentation contains a reference to a DoD contract number or a military destination.

U.S.-flag vessel means either a vessel belonging to the United States or a vessel of the United States as that term is defined in 46 U.S.C. 116.

* * * * *

(d) The Contractor and its subcontractors may request, via the Contracting Officer, a waiver of the requirement to use a U.S.-flag vessel, or identification of any available U.S.-flag vessels, if the Contractor or a subcontractor sufficiently explains that—

(1) U.S.-flag vessels are not available at a fair and reasonable rate for commercial vessels of the United States; or

(2) U.S.-flag vessels are otherwise not available.

(e) * * * The Contracting Officer will process requests submitted after such date(s) as expeditiously as possible, however, if a DoD waiver is not approved prior to the shipper's sailing date, this will not of itself constitute a compensable delay under this or any other clause of this contract. * * *

* * * * *

(7) A documented description of current, diligent efforts made to secure U.S.-flag vessels, including points of contact (with names and telephone numbers) with at least two U.S.-flag carriers contacted. Copies of quotes will suffice for this purpose. Copies of telephone notes, emails, and other relevant communications will otherwise be considered for this purpose.

* * * * *

Alternate II. * * *

(a) *Definitions.* As used in this clause—

Foreign-flag vessel means any vessel that is not a U.S.-flag vessel.

Ocean transportation means any water-borne transportation aboard a ship, vessel, boat, barge, ferry, or the like outside the internal waters of the United States as defined in 33 CFR 2.24.

Subcontractor means a supplier, materialman, distributor, or vendor at any level below the prime contractor

whose contractual obligation to perform results from, or is conditioned upon, award of the prime contract and who is performing any part of the work or other requirement of the prime contract.

Supplies means supplies that are clearly identifiable for eventual use by or owned by DoD at the time of transportation by sea, or are otherwise transported by DoD, regardless of ownership or use by DoD. An item is clearly identifiable for eventual use by DoD if, for example, the contract documentation contains a reference to a DoD contract number or a military destination.

U.S.-flag vessel means either a vessel belonging to the United States or a vessel of the United States as that term is defined in 46 U.S.C. 116.

* * * * *

(d) The Contractor and its subcontractors may request, via the Contracting Officer, a waiver of the requirement to use a U.S.-flag vessel, or identification of any available U.S.-flag vessels, if the Contractor or a subcontractor sufficiently explains that—

(1) U.S.-flag vessels are not available at a fair and reasonable rate for commercial vessels of the United States; or

(2) U.S.-flag vessels are otherwise not available.

(e) * * * The Contracting Officer will process requests submitted after such date(s) as expeditiously as possible, however, if a DoD waiver is not approved prior to the shipper's sailing date, this will not of itself constitute a compensable delay under this or any other clause of this contract. * * *

(7) A documented description of current, diligent efforts made to secure U.S.-flag vessels, including points of contact (with names and telephone numbers) with at least two U.S.-flag carriers contacted. Copies of quotes will suffice for this purpose. Copies of telephone notes, emails, and other relevant communications will otherwise be considered for this purpose.

* * * * *

■ 8. Revise section 252.247–7025 to read as follows:

252.247–7025 Reflagging or Repair Work.

As prescribed in 247.574(b), use the following clause:

Reflagging or Repair Work (OCT 2024)

(a) *Definitions.* As used in this clause—

Corrective and preventive maintenance or repair means—

(1) Maintenance or repair actions performed as a result of a failure in order to return or restore equipment to acceptable performance levels; and

(2) Scheduled maintenance or repair actions to prevent or discover functional failures.

Reflagging or repair work means work performed on a vessel—

(1) To enable the vessel to meet applicable standards to become a vessel of the United States; or

(2) To convert the vessel to a more useful military configuration.

(b) *Requirement.* Unless DoD waives this requirement, the Contractor shall ensure performance of the following in the United States or its outlying areas:

(1) Reflagging or repair work, if the reflagging or repair work is performed—

(i) On a vessel for which the Contractor submitted an offer in response to the solicitation for this contract; and

(ii) Prior to acceptance of the vessel by the Government.

(2) Corrective and preventive maintenance or repair work for the duration of the contract, to the greatest extent practicable.

(End of clause)

■ 9. Amend section 252.247–7026—

■ a. By revising the provision date;

■ b. In paragraph (a) by revising the definition of “Covered vessel” and removing the definition of “Shipyard”;

■ c. In paragraph (b) and paragraph (c) introductory text by removing “offeror” and adding “Offeror” in its place;

■ d. In paragraph (e) by removing “Section 1017 of Public Law 109–364” and adding “section 1017 of Public Law 109–364 (10 U.S.C. 2631 note)” in its place.

The revisions read as follows:

252.247–7026 Evaluation Preference for Use of Domestic Shipyards—Applicable to Acquisition of Carriage by Vessel for DoD Cargo in the Coastwise or Noncontiguous Trade.

* * * * *

Evaluation Preference for Use of Domestic Shipyards—Applicable To Acquisition of Carriage by Vessel for DOD Cargo in the Coastwise or Noncontiguous Trade (OCT 2024)

(a) * * *

Covered vessel means a vessel—

(1) Owned, operated, or controlled by the offeror; and

(2) Qualified to engage in the carriage of cargo in the coastwise or noncontiguous trade under 46 U.S.C. 12112 and 50501 and 46 U.S.C. chapter 551.

* * * * *

[FR Doc. 2024–21092 Filed 9–25–24; 8:45 am]

BILLING CODE 6820–FR–P

DEPARTMENT OF DEFENSE**Defense Acquisition Regulations System****48 CFR Parts 212, 215, 225, and 252****[Docket DARS–2024–0002]****RIN 0750–AL64****Defense Federal Acquisition Regulation Supplement: Assuring Integrity of Overseas Fuel Supplies (DFARS Case 2022–D013)****AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).**ACTION:** Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2022 that requires offerors to certify that they will not provide fuel from a prohibited source and that they will comply with certain export control and anticorruption regulations and statutes for contracts awarded for the acquisition of fuel in support of overseas contingency operations.

DATES: Effective October 1, 2024.**FOR FURTHER INFORMATION CONTACT:** Mr. Jon Snyder, telephone 703–945–5341.**SUPPLEMENTARY INFORMATION:****I. Background**

DoD published a proposed rule in the *Federal Register* at 89 FR 11800 on February 15, 2024, to implement section 843 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81). Section 843 requires offerors to certify that fuel to be provided for a contract in support of an overseas contingency operation is not sourced from a prohibited nation or region and to furnish such records as are necessary to verify their compliance with applicable export control and anticorruption regulations and statutes. Section 843 requires contracting officers, when conducting a source selection for such contracts, to consider using tradeoff processes and certain evaluation factors. If the contracting officer does not consider a tradeoff process prior to issuing the solicitation, the contracting officer is required to justify in writing why a tradeoff process was not considered. Section 843 also requires the contracting officer to ensure, prior to contract award, that the offeror is not disqualified based upon an unsupported denial of access to a facility or equipment by the host nation. One respondent submitted public

comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

There are no significant changes from the proposed rule.

B. Analysis of Public Comments**1. Support for the Rule**

Comment: The respondent expressed support for the rule.

Response: DoD acknowledges the respondent's support for the rule.

2. Clarifications

Comment: The respondent recommended the rule include Russia as a prohibited source and questioned how a contracting officer would know if an offeror is proposing fuel from Russia or not. The respondent suggested that the rule should better clarify the definition and identification of prohibited sources of fuel and include Russia among them.

Response: This rule implements section 843 of the NDAA for FY 2022, which does not establish a specific list of prohibited countries, entities, or individuals. This rule specifies, at DFARS 225.7024–2, a prohibition on procuring fuel sourced from nations or regions that are prohibited from selling petroleum to the United States (*i.e.*, prohibited sources). These prohibited sources are identified in FAR subpart 25.7 and at <https://ofac.treasury.gov/sanctions-programs-and-country-information>; therefore, it is not necessary to identify Russia as a prohibited source in this rule. The website is added to the final rule at DFARS 225.7024–2.

Comment: The respondent expressed concerns regarding the fungibility of fuel and the possibility of laundering fuel from a prohibited source through an allowable fuel storage system. The respondent suggests that the rule require offerors to provide documentation or evidence of the origin and quality of the fuel they supply, such as bills of lading, certificates of origin, or laboratory tests.

Response: The rule adds a new solicitation provision at DFARS 252.225–7065, Restriction on Acquisition of Fuel for Overseas Contingency Operations, which requires offerors to certify that the fuel, in whole or in part, or derivatives of such fuel, to be provided under any contract resulting from this solicitation is not

sourced from a nation or region prohibited from selling petroleum to the United States. This rule implements section 843 of the NDAA for FY 2022, which does not require offerors to provide documentation to support such certifications.

Comment: The respondent suggested that the rule might leverage the logistics information technologies to track and monitor the fuel supply chain to identify any anomalies or discrepancies and enforce more strictly the applicability of certain laws and regulations, such as the Foreign Corrupt Practices Act and the Export Administration Regulations, to deter and punish any violations or corruption in the fuel acquisition process.

Response: Section 843 specifies that the contracting officer will obtain certain certifications from offerors regarding their compliance with certain preaward requirements prior to awarding a contract. As a result of this rule, the offeror is required to certify the fuel to be provided under the resulting contract is not sourced from nations or regions prohibited from selling petroleum to the United States.

There are several mandatory solicitation provisions and contract clauses that require contractors to comply with all applicable laws and regulations regarding export-controlled items, *e.g.*, International Traffic in Arms Regulations and Export Administration Regulations. This responsibility exists independent of, and is not established or limited by, this rule.

C. Other Changes

At DFARS 225.7024–3 and 252.225–7065, editorial changes are made to use the term “prospective contractor” in place of “apparent successful offeror” to comply with drafting conventions. The terms have the same meaning.

III. Applicability to Contracts At or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

The provision at DFARS 252.225–7065 is prescribed at DFARS 225.7024–4 for use in solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial products and commercial services, that are for the acquisition of fuel for overseas contingency operations and are expected to exceed the simplified acquisition threshold. Consistent with the analysis that DoD provided in the proposed rule with regard to the application of the requirements of section 843 of the

NDAA for FY 2022, DoD has made the determination to apply the statute, as implemented in the provision at DFARS 252.225–7065, to contracts for the acquisition of commercial products including COTS items and to the acquisition of commercial services, as defined at Federal Acquisition Regulation 2.101.

IV. Expected Impact of the Rule

As a result of this final rule, offerors responding to a solicitation for fuel, that is for an overseas contingency operation and that is expected to exceed the SAT, are now required to certify that the proposed fuel, in whole or in part, or derivatives of such fuel will not be sourced from a nation or region prohibited from selling petroleum to the United States. Offerors will also be required to comply with certain export control and anticorruption statutes and regulations. The prospective contractor may be requested to provide records to verify such compliance upon contracting officer request.

This final rule also imposes new requirements on contracting officers. Contracting officers must not disqualify an offeror based on an unsupported denial of access to a facility or equipment by a host nation government. When conducting a source selection for such acquisitions, contracting officers will be required to consider the use of a tradeoff process and the use of certain evaluation factors. If the contracting officer does not consider a tradeoff process, the contracting officer must justify and obtain approval of the rationale for not considering a tradeoff process.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or

final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VII. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

This rule is necessary to implement section 843 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81). Section 843 requires offerors to certify that the fuel procured for an overseas contingency operation is not sourced from a prohibited nation or region and to furnish such records as are necessary to verify their compliance with certain export control and anticorruption statutes and regulations. Section 843 requires contracting officers to consider a tradeoff process and the use of certain evaluation factors when procuring fuel for an overseas contingency operation. If the contracting officer does not consider a tradeoff process, section 843 requires the contracting officer to justify, before issuing the solicitation, why a tradeoff process was not considered. The objective of the rule is to implement section 843 of the NDAA for FY 2022.

There were no significant issues raised by the public in response to the initial regulatory flexibility analysis.

Data from the Federal Procurement Data System was analyzed for fiscal years 2021, 2022, and 2023 for DoD contracts awarded to procure fuel for overseas operations. The data revealed there was an average of five awards per fiscal year for the procurement of fuel supporting overseas operations. These awards were made to three unique entities, of which none were small entities. Therefore, DoD does not anticipate that this final rule will impact any small entities.

The rule does not impose any new reporting, recordkeeping, or other compliance requirements for small entities.

There are no known alternatives that would accomplish the stated objectives of the applicable statute. The rule is not expected to have a significant economic impact on small entities.

VIII. Paperwork Reduction Act

This final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 212, 215, 225, and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System amends 48 CFR parts 212, 215, 225, and 252 as follows:

■ 1. The authority citation for parts 212, 215, 225, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 2. Amend section 212.203 by adding paragraph (5) to read as follows:

212.203 Procedures for solicitation, evaluation, and award.

* * * * *

(5) See 215.101–71 and 225.7024 for the acquisition of fuel for overseas contingency operations.

■ 3. Amend section 212.301 by adding paragraph (f)(x)(PP) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

(f) * * *

(x) * * *

(PP) Use the provision at 252.225–7065, Restriction on Acquisition of Fuel for Overseas Contingency Operations, as prescribed in 225.7024–4, to comply with section 843 of the National Defense Authorization Act for Fiscal Year 2022 (Pub. L. 117–81).

* * * * *

PART 215—CONTRACTING BY NEGOTIATION

■ 4. Add section 215.101–71 to read as follows:

215.101–71 Tradeoff process when acquiring fuel for overseas contingency operations.

(a) When conducting a source selection for the acquisition of fuel that is for an overseas contingency operation and is expected to exceed the simplified acquisition threshold, the contracting

officer shall consider using a tradeoff process in accordance with FAR 15.101–1 (section 843 of the National Defense Authorization Act for Fiscal Year 2022 (Pub. L. 117–81)). The contracting officer should consider using the following evaluation factors in any such tradeoff process:

- (1) Past performance.
- (2) Cost.
- (3) Anticorruption training.
- (4) Anticorruption compliance.

(b) If a tradeoff process was not considered, prior to the issuance of the solicitation, the contracting officer shall justify in writing why a tradeoff process was not considered and obtain approval by an official one level above the contracting officer. This authority is not delegable. The contracting officer shall include the justification in the contract file.

PART 225—FOREIGN ACQUISITION

■ 5. Add sections 225.7024, 225.7024–1, 225.7024–2, 225.7024–3, and 225.7024–4 to read as follows:

* * * * *

Sec.

225.7024 Restriction on acquisition of fuel for overseas contingency operations.

225.7024–1 Scope.

225.7024–2 Prohibition.

225.7024–3 Procedures.

225.7024–4 Solicitation provision.

* * * * *

225.7024 Restriction on acquisition of fuel for overseas contingency operations.

225.7024–1 Scope.

This section implements section 843 of the National Defense Authorization Act for Fiscal Year 2022 (Pub. L. 117–81), for the acquisition of fuel for overseas contingency operations.

225.7024–2 Prohibition.

Contracting officers shall not award, for an overseas contingency operation, a contract for fuel, in whole or in part, or derivatives of such fuel, that is sourced from nations or regions prohibited from selling petroleum to the United States. See FAR subpart 25.7 and the Office of Foreign Assets Control website at <https://ofac.treasury.gov/sanctions-programs-and-country-information> for prohibited sources.

225.7024–3 Procedures.

(a) For contracts for the acquisition of fuel for overseas contingency operations, including contracts using FAR part 12 procedures, expected to exceed the simplified acquisition threshold, the contracting officer—

- (1) May request records from the prospective contractor to verify

compliance with the following statutes and regulations only when the head of the contracting activity determines in writing that it is necessary:

(i) The Foreign Corrupt Practices Act (15 U.S.C. 78dd–1 *et seq.*).

(ii) International Traffic in Arms Regulations at 22 CFR parts 120 through 130 (see PGI 225.7901–2).

(iii) Export Administration Regulations at 15 CFR parts 730 through 774 (see PGI 225.7901–2).

(iv) Relevant regulations promulgated by the Office of Foreign Assets Control of the Department of the Treasury. Sanction information for specific countries and programs is available at <https://ofac.treasury.gov/sanctions-programs-and-country-information>.

(2) To the maximum extent practicable, shall not disqualify an otherwise responsible offeror on the basis of an unsupported denial of access to a facility or equipment by a host-nation government. The provision at 252.225–7065, Restriction on Acquisition of Fuel for Overseas Contingency Operations, requires offerors to report promptly to the contracting officer, prior to award, any instance of unsupported denial of access to a facility or equipment by a host-nation government that may prevent it from complying with the terms and conditions of the solicitation.

(b) See 215.101–71 for the requirement to consider using a tradeoff process.

225.7024–4 Solicitation provision.

Use the provision at 252.225–7065, Restriction on Acquisition of Fuel for Overseas Contingency Operations, in solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial products and commercial services, that are for the acquisition of fuel for overseas contingency operations and are expected to exceed the simplified acquisition threshold.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 6. Add section 252.225–7065 to read as follows:

252.225–7065 Restriction on Acquisition of Fuel for Overseas Contingency Operations.

As prescribed in 225.7024–4, use the following provision:

Restriction on Acquisition of Fuel for Overseas Contingency Operations (Oct 2024)

- (a) *Prohibition.* For an overseas contingency operation, DoD may not procure

fuel in whole or in part, or derivatives of such fuel, that is sourced from nations or regions prohibited from selling petroleum to the United States. See Federal Acquisition Regulation subpart 25.7 and the Office of Foreign Assets Control website at <https://ofac.treasury.gov/sanctions-programs-and-country-information> for prohibited sources.

(b) *Certification.* Offerors shall complete the certification in paragraph (b)(1) of this provision and submit the certification with their offer.

(1) The Offeror does [] does not [] certify that the fuel, in whole or in part, or derivatives of such fuel, to be provided under any contract resulting from this solicitation is not sourced from a nation or region prohibited from selling petroleum to the United States.

(2) Only Offerors who certify that the fuel to be provided is not sourced from a prohibited nation or region will be eligible for award.

(c) *Compliance.*

(1) When requested by the Contracting Officer, the prospective Contractor shall submit records necessary to demonstrate compliance with applicable laws and regulations regarding export-controlled items and anticorruption statutes and regulations including—

(i) The Foreign Corrupt Practices Act (15 U.S.C. 78dd–1 *et seq.*);

(ii) International Traffic in Arms Regulations (ITAR) at 22 CFR parts 120 through 130 (also see Defense Federal Acquisition Regulation Supplement (DFARS) clause 252.225–7048, Export-Controlled Items);

(iii) Export Administration Regulations (EAR) at 15 CFR parts 730 through 774 (also see DFARS clause 252.225–7048); and

(iv) Relevant regulations promulgated by the Office of Foreign Assets Control of the Department of the Treasury. Sanction information for specific countries and programs is available at <https://ofac.treasury.gov/sanctions-programs-and-country-information>.

(2) The Offeror shall contact the Department of State regarding ITAR compliance and the Department of Commerce regarding EAR compliance.

(d) *Reporting requirement.* The Offeror shall, prior to contract award, promptly report to the Contracting Officer any instance of unsupported denial of access to a facility or equipment by a host-nation government that may prevent it from complying with the terms and conditions of the solicitation.

(End of provision)

[FR Doc. 2024–21093 Filed 9–25–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE**Defense Acquisition Regulations System****48 CFR Part 206**

[Docket DARS–2024–0014]

RIN 0750–AL65

Defense Federal Acquisition Regulation Supplement: Modification of Prize Authority for Advanced Technology Achievements (DFARS Case 2022–D014)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2022 that provides procedures and approval and reporting requirements for contracts awarded as prizes for advanced technology achievements.

DATES: Effective October 1, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Jon Snyder, telephone 703–945–5341.

SUPPLEMENTARY INFORMATION:**I. Background**

DoD published a proposed rule in the **Federal Register** at 89 FR 31680 on April 25, 2024, to implement section 822 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81), which amends 10 U.S.C. 4025. Section 822 provides the authority to carry out advanced technology prize programs to award contracts to recognize outstanding achievements in basic, advanced, and applied research; technology development; and prototype development. Section 822 specifies the award of a contract as a prize is a competitive procedure if the solicitation is widely advertised. Section 822 also requires approval of such awards that exceed \$10,000 and congressional reporting for contracts that exceed \$10 million. There were no public comments submitted in response to the proposed rule. There are no changes made to the final rule.

II. Applicability to Contracts At or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This final rule does not create any new solicitation provisions or contract clauses. It does not impact any existing solicitation provisions or contract clauses or their applicability to contracts valued at or below the simplified acquisition threshold, for commercial products including COTS items, or for commercial services.

III. Expected Impact of the Rule

Prior to the enactment of the NDAA for FY 2022, 10 U.S.C. 4025 (formerly 10 U.S.C. 2374a) did not provide for the award of contracts as prizes for outstanding achievements in basic, advanced, and applied research; technology development; and prototype development. This final rule implements the authority to award contracts as prizes under certain conditions.

This final rule may increase participation in prize competitions and decrease the lead time to deliver to the warfighter achievements in basic, advanced, and applied research; technology development; and prototype development. This final rule may help to expand the defense industrial base by providing a way for entities that are new to DoD procurement to obtain DoD contracts. It may also streamline the competitive process, which could reduce Government administrative costs associated with competitive negotiated acquisitions. For this reason, the difference in the cost of managing a contract instead of another type of prize is expected to be negligible.

Data provided from the Office of the Under Secretary of Defense for Research and Engineering indicates there were a total of 809 cash prizes awarded from FY 2021 to FY 2023, or approximately 270 per year, worth a total of about \$3.5 million annually. DoD estimates 20 percent of these 270 historical cash prize awards, or 54 cash prize awards worth a total of approximately \$700,000, would be converted to contracts. Therefore, DoD estimates that approximately 54 entities per year would be awarded contracts or a combination of contracts, other agreements (e.g., grants, cooperative agreements, other transaction agreements), and cash prizes as a result of the changes in this final rule.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VI. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

This rule is necessary to implement section 822 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81), which amends 10 U.S.C. 4025, Prizes for advanced technology achievements. Section 822 provides advanced technology prize programs authority to award contracts to recognize outstanding achievements in basic, advanced, and applied research; technology development; and prototype development. Section 822 also provides that the award of a contract as a prize is a competitive procedure if the prize program solicitation is widely advertised. Section 822 also requires approval of such awards exceeding \$10,000 and congressional reporting for contracts exceeding \$10 million. The objective of this final rule is to implement section 822 of the NDAA for FY 2022.

There were no significant issues raised by the public in response to the initial regulatory flexibility analysis.

Data provided from the Office of the Under Secretary of Defense for Research and Engineering indicates there were a

total of 809 cash prizes awarded from FY 2021 to FY 2023, or approximately 270 per year, worth a total of about \$3.5 million annually. During this three-year period, DoD awarded a total of 636 cash prizes to small entities, which is an average of 212 per year. DoD estimates 20 percent of these 212 historical cash prize awards, or 42 cash prize awards worth a total of approximately \$545,000, would be converted to contracts. Therefore, DoD estimates that approximately 42 small entities per year would be awarded contracts or a combination of contracts, other agreements (e.g., grants, cooperative agreements, other transaction agreements), and cash prizes as a result of the changes in this final rule. Therefore, DoD does not anticipate that this final rule will have a significant impact on small entities.

The rule does not impose any new reporting, recordkeeping, or other compliance requirements for small entities.

There are no known alternatives that would accomplish the stated objectives of the applicable statute.

VII. Paperwork Reduction Act

This final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 206

Government procurement.

Jennifer D. Johnson,
Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System amends 48 CFR part 206 as follows:

PART 206—COMPETITION REQUIREMENTS

■ 1. The authority citation for 48 CFR part 206 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend section 206.102–70 by—
■ a. Designating the text as paragraph (a); and
■ b. Adding paragraph (b).

The addition reads as follows:

206.102–70 Other competitive procedures.

(a) * * *

(b) The award of a contract as a prize resulting from a competitive selection of prize recipients for advanced technology achievements is a competitive procedure (10 U.S.C. 4025(f)), when the solicitation is widely

advertised, including through the Governmentwide point of entry (see FAR part 5). See PGI 206.102–70 for approval requirements.

[FR Doc. 2024–21094 Filed 9–25–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 204 and 217

[Docket DARS–2024–0030]

RIN 0750–AL70

Defense Federal Acquisition Regulation Supplement: Data Universal Numbering System to Unique Entity Identifier Transition (DFARS Case 2022–D023)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to align the DFARS with the Federal Acquisition Regulation (FAR) transition from the Data Universal Numbering System to the unique entity identifier in the System for Award Management.

DATES: Effective October 1, 2024.

FOR FURTHER INFORMATION CONTACT: Tonya DeSaussure, telephone 202–805–1388.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is issuing a final rule amending the DFARS to transition from the use of the Data Universal Numbering System (DUNS) number to the unique entity identifier as a means of identifying Federal contractors. The FAR published a final rule implementing the change from the DUNS number to the unique entity identifier in the **Federal Register** on November 18, 2015 (80 FR 72035). As a supplement to the FAR, the DFARS is required to reflect the same terminology. The unique entity identifier is the authoritative identifier at the Federal level. This transition allows the Government to streamline the entity identification and validation process, making it easier and less burdensome on entities to do business with the Federal Government.

II. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707, Publication of Proposed Regulations. Subsection (a)(1) of the statute requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because there is no significant cost or administrative impact on contractors or offerors. The FAR already requires contractors and offerors to use a unique entity identifier; this final rule merely updates the terminology used in the DFARS.

III. Applicability to Contracts At or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This final rule does not create any new solicitation provisions or contract clauses. It does not impact any existing solicitation provisions or contract clauses or their applicability to contracts valued at or below the simplified acquisition threshold, for commercial products including COTS items, or for commercial services.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD

will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

VII. Paperwork Reduction Act

This final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 204 and 217

Government procurement.

Jennifer D. Johnson,
Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System amends 48 CFR parts 204 and 217 as follows:

- 1. The authority citation for 48 CFR parts 204 and 217 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 204—ADMINISTRATIVE AND INFORMATION MATTERS

204.1103 [Amended]

- 2. Amend section 204.1103—

- a. In paragraph (1) by removing “(SAM)” and adding “SAM” in its place;
- b. In paragraph (2)(ii) by removing “Data Universal Numbering System (DUNS) number” and adding “unique entity identifier (UEI)” in its place;
- c. In paragraph (3) by removing “DUNS number” and adding “UEI” in its place; and
- d. In paragraph (5) by removing “DUNS number or DUNS+4 number” and adding “UEI” in its place.

PART 217—SPECIAL CONTRACTING METHODS

217.207 [Amended]

- 3. Amend section 217.207 in paragraph (c)(1) by removing “Data Universal Numbering System (DUNS) number” and adding “unique entity identifier” in its place.

[FR Doc. 2024–21095 Filed 9–25–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 201 and 204

[Docket DARS–2024–0001]

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule; technical amendment.

SUMMARY: DoD is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to make needed editorial changes.

DATES: Effective October 1, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer D. Johnson, Defense

Acquisition Regulations System, telephone 703–717–8226.

SUPPLEMENTARY INFORMATION: This final rule amends the DFARS to make needed editorial changes to update an email address at DFARS 201.170 and to remove DFARS subpart 204.70, Procurement Acquisition Lead Time. This subpart consisted of a pointer to DFARS Procedures, Guidance, and Information, which is no longer needed.

List of Subjects in 48 CFR Parts 201 and 204

Government procurement.

Jennifer D. Johnson,
Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System amends 48 CFR parts 201 and 204 as follows:

- 1. The authority citation for 48 CFR parts 201 and 204 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 201—FEDERAL ACQUISITION REGULATIONS SYSTEM

201.170 [Amended]

- 2. Amend section 201.170 in paragraph (a)(2)(ii) by removing “osd.pentagon.ousd-a-s.mbx.dpc-pcf@mail.mil” and adding “osd.pentagon.ousd-a-s.mbx.dpc-pcf-peer-reviews@mail.mil” in its place.

PART 204—ADMINISTRATIVE AND INFORMATION MATTERS

Subpart 204.70 [Removed and Reserved]

- 3. Remove and reserve subpart 204.70, consisting of section 204.7001.

[FR Doc. 2024–21096 Filed 9–25–24; 8:45 am]

BILLING CODE 6820–FR–P

DEPARTMENT OF DEFENSE**Defense Acquisition Regulations System****48 CFR Parts 235 and 252****[Docket DARS–2024–0027]****RIN 0750–AL43****Defense Federal Acquisition Regulation Supplement: Public Access to Results of Federally Funded Research (2020–D028)****AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).**ACTION:** Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a recommendation of the Government Accountability Office regarding DoD-funded fundamental research.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before November 25, 2024, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2020–D028, using either of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Search for DFARS Case 2020–D028. Select “Comment” and follow the instructions to submit a comment. Please include “DFARS Case 2020–D028” on any attached documents.

- *Email:* osd.dfars@mail.mil. Include DFARS Case 2020–D028 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. To confirm receipt of your comment(s), please check <https://www.regulations.gov>, approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Mr. Jon M. Snyder, telephone 703–945–5341.

SUPPLEMENTARY INFORMATION:**I. Background**

DoD is proposing to revise the DFARS to implement a recommendation made by the Government Accountability Office (GAO) in its report GAO–20–81, *Additional Actions Needed to Improve Public Access to Research Results*, published in November 2019. GAO reviewed the progress agencies have

made in implementing their plans to increase public access to Federally funded research results (publications and data), as called for in a 2013 Office of Science and Technology Policy (OSTP) memorandum. In this report, GAO recommended that DoD take steps to ensure appropriate agency-funded research data are readily findable and accessible to the public.

The OSTP memorandum of February 22, 2013, entitled “Increasing Access to the Results of Federal Funded Scientific Research”, directed that each Federal agency with over \$100 million in annual research and development expenditures develop a plan to support increased public access to the results of research funded by the Federal Government. This includes any results published in peer-reviewed scholarly publications that are based on research that directly arises from Federal funds. The required plan’s objectives were developed with input from the National Science and Technology Council and public consultation in compliance with the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

II. Discussion and Analysis

This rule proposes changes to DFARS part 235 and adds two clauses that require contractors to submit final peer-reviewed manuscripts to the Defense Technical Information Center’s publicly accessible repository and to develop and maintain a data management plan.

Definitions are proposed at DFARS 235.001 for “data”, “data management plan”, “fundamental research”, and “peer-reviewed”. A policy statement reflects that for DoD-funded fundamental research, data management planning must be an integral part of research planning as required by Department of Defense Instruction 3200.12, DoD Scientific and Technical Information Program (STIP). DFARS 235.011 provides guidance for the submission of peer-reviewed manuscripts and development and submission of data management plans. Prescriptions are added at DFARS 235.072 for the following new DFARS part 252 contract clauses: (1) 252.235–70XX, Peer-Reviewed Manuscripts; and (2) 252.235–70YY, Data Management Plan. The clauses apply to solicitations and contracts that include fundamental research funded in whole or in part by DoD.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This proposed rule proposes to create two new clauses: (1) DFARS 252.235–70XX, Peer-Reviewed Manuscripts; and (2) DFARS 252.235–70YY, Data Management Plan. The clauses at DFARS 252.235–70XX and 252.235–70YY are prescribed at DFARS 235.702 for use in research and development solicitations and contracts that include fundamental research funded in whole or in part by DoD. The clauses are applicable to contracts at or below the SAT. The clauses are not applicable to contracts for the acquisition of commercial products including COTS items and for the acquisition of commercial services. Not applying the clauses to contracts valued at or below the SAT would exclude contracts intended to be covered by this proposed rule and undermine the overarching purpose of the proposed rule, given GAO’s recommendation that DoD take steps to ensure appropriate agency-funded research data are readily findable and accessible to the public.

IV. Expected Impact of the Rule

The Defense Technical Information Center is responsible for collecting all scientific and technical reports. This proposed rule, when finalized, will require contractors under research and development contracts that include fundamental research, funded in whole or in part by DoD, to submit the author’s final peer-reviewed manuscript to one of the Defense Technical Information Center’s publicly accessible repositories.

Currently, a contractor’s data management plan is not required for research and development contracts. The proposed rule, when finalized, will require contractors awarded research and development contracts to implement and maintain a data management plan throughout the performance of the contract.

This proposed rule will ensure the results of fundamental research, funded in whole or in part by DoD, will be made as widely available as permitted by law, regulation, or policy to ensure the accuracy, validity, and reproducibility of the scientific results.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Regulatory Flexibility Act

DoD does not expect this proposed rule, when finalized, to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because it is limited to contracts for DoD funded fundamental research. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a recommendation made by the Government Accountability Office (GAO) in Report GAO–20–81, Additional Actions Needed to Improve Public Access to Research Results, published in November 2019. GAO reviewed the progress agencies have made in implementing their plans to increase public access to Federally funded research results (publications and data), as called for in a 2013 Office of Science and Technology Policy (OSTP) memorandum. In this report, GAO recommended that DoD take steps to ensure appropriate agency-funded research data are readily findable and accessible to the public.

The OSTP memorandum of February 22, 2013, entitled “Increasing Access to the Results of Federal Funded Scientific Research,” directed that each Federal agency with over \$100 million in annual research and development expenditures develop a plan to support increased public access to the results of research funded by the Federal Government. This includes any results published in peer-reviewed scholarly publications that are based on research that directly arises from Federal funds. The required plan’s objectives were developed with input from the National Science and Technology Council and public consultation in compliance with the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

The objective of this proposed rule is to implement the recommendation to DoD in the GAO report GAO–20–81.

The legal basis for this proposed rule is 41 U.S.C. 1303.

Data was obtained on contracts that include DFARS clause 252.235–7011, Final Scientific or Technical Report. This DFARS clause is required to be included in solicitations and contracts for research and development, which includes fundamental research. According to the Procurement Business Intelligence Service in the last three fiscal years, DoD awarded contracts including this clause to unique small entities as follows: 2,086 in fiscal year (FY) 2021, 2,389 in FY 2022, and 1,799 in FY 2023, which averages out to 2,091 per FY. Therefore, the number of small entities to which this proposed rule may apply is approximately 2,091.

This proposed rule does not impose any new reporting, recordkeeping, or other compliance requirements for small entities.

This proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known alternatives that would accomplish the stated objectives of the applicable policy.

DoD invites comments from small business concerns and other interested parties on the expected impact of this proposed rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this proposed rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2020–D028), in correspondence.

VII. Paperwork Reduction Act

This proposed rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 235 and 252

Government procurement.

Jennifer D. Johnson,
Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System proposes to amend 48 CFR parts 235 and 252 as follows:

■ 1. The authority citation for 48 CFR parts 235 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 235—RESEARCH AND DEVELOPMENT CONTRACTING

■ 2. Amend section 235.001 by—

- a. Adding introductory text; and
- b. Adding, in alphabetical order, the definitions for “Data”, “Data management plan”, “Fundamental research”, and “Peer-reviewed”.

The additions read as follows:

235.001 Definitions.

As used in this subpart—

Data means the digitally recorded factual material commonly accepted in the scientific community as necessary to validate research findings, including data sets used to support scholarly publications including publicly releasable digital data, algorithms, or other information central to the conclusions of published peer-reviewed scientific research.

Data management plan means a document that describes which data generated during performance of a research and development contract will be publicly shared and preserved and how it will be accomplished, or a justification of why such actions cannot be accomplished.

Fundamental research means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons. (Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)) memorandum on Fundamental Research, dated May 24, 2010)

Peer-reviewed means a process that subjects an author’s scholarly work, research, or ideas to the scrutiny of others who are experts in the same field and is considered necessary to ensure scientific quality.

* * * * *

■ 3. Add section 235.003 to read as follows:

235.003 Policy.

It is DoD policy that for DoD-funded fundamental research (see 204.403(2)), data management planning should be an integral part of research planning. See Department of Defense Instruction 3200.12, DoD Scientific and Technical Information Program.

■ 4. Add section 235.010–70 to read as follows:

235.010–70 Peer-reviewed manuscripts.

The contracting officer shall require the contractor to submit peer-reviewed manuscripts as required by the clause at 252.235–70XX, Peer-Reviewed Manuscripts.

■ 5. Add section 235.011 to read as follows:

235.011 Data.

(1) The contracting officer shall obtain a data management plan from the contractor at the start of the research project as required by the clause at 252.235–70YY, Data Management Plan.

(2) The contracting officer shall provide the contractor's data management plan to the program manager for approval and notify the contractor of such approval or disapproval.

■ 6. Amend section 235.072 by adding paragraphs (f) and (g) to read as follows:

235.072 Additional contract clauses.

* * * * *

(f) Use the clause at 252.235–70XX, Peer-Reviewed Manuscripts, in solicitations and contracts for research and development that include fundamental research funded in whole or in part by DoD.

(g) Use the clause at 252.235–70YY, Data Management Plan, in solicitations and contracts for research and development that include fundamental research funded in whole or in part by DoD.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 7. Add sections 252.235–70XX and 252.235–70YY to read as follows:

252.235–70XX Peer-Reviewed Manuscripts.

As prescribed in 235.072(f), use the following clause:

Peer-Reviewed Manuscripts (DATE)

(a) *Definitions.* As used in this clause—
Final peer-reviewed manuscript means an author's final manuscript of a peer-reviewed paper accepted for journal publication, including all modifications from the peer-review process and manuscripts jointly authored with DoD personnel during the period of performance of the fundamental research contract. It does not include reports required to be delivered under the terms of the contract.

Peer-reviewed means a process that subjects an author's scholarly work, research, or ideas to the scrutiny of others who are experts in the same field and is considered necessary to ensure scientific quality.

(b) *Submission of final peer-reviewed manuscript.* When the final title and date of publication of the author's final peer-reviewed manuscript are known, the Contractor shall submit an electronic copy of the manuscript to one of the following Defense Technical Information Center repositories:

(1) Contractors with a common access card (CAC), personal identity verification (PIV), or external certification authority (ECA) shall

submit to <https://discover.dtic.mil/submit-documents/>; or

(2) Contractors without a CAC, PIV, or ECA shall submit to <https://www.osti.gov/elink/agency-submission>.

(End of clause)

252.235–70YY Data Management Plan.

As prescribed in 235.072(g), insert the following clause:

Data Management Plan (DATE)

(a) *Definitions.* As used in this clause—
Data means the digitally recorded factual material commonly accepted in the scientific community as necessary to validate research findings, including data sets used to support scholarly publications including publicly releasable digital data, algorithms, or other information central to the conclusions of published peer-reviewed scientific research.

Data management plan means a document that describes which data generated during performance of a research and development contract will be publicly shared and preserved and how it will be accomplished, or a justification of why such actions cannot be accomplished.

(b) *Submission of data management plan.* Within 30 days of contract award, the Contractor shall submit to the Contracting Officer, with a copy to the Contracting Officer's Representative and the Program Manager, a data management plan for approval by the Program Manager. Generally, the data management plan should not exceed 2 pages and should address elements relevant to the research discipline for the following areas (see DoD Instruction 3200.12):

(1) The types of data, software, and other materials to be produced.

(2) How the data will be acquired.

(3) Time and location of data acquisition, if scientifically pertinent.

(4) How the data will be processed.

(5) The file formats and the naming conventions that will be used.

(6) A description of the quality assurance and quality control measures during collection, analysis, and processing.

(7) A description of dataset origin when existing data resources are used.

(8) A description of the standards to be used for data and metadata format and content.

(9) Appropriate timeframe for preservation.

(10) The plan may consider the balance between the relative value of data preservation and other factors such as the associated cost and administrative burden. The plan will provide a justification for such decisions.

(11) A statement that the data cannot be made available to the public when there are national security or controlled unclassified information concerns.

(c) *Implementation and maintenance of the data management plan.* The Contractor shall implement and maintain the approved data management plan throughout the performance of the contract.

(End of clause)

[FR Doc. 2024–21097 Filed 9–25–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 214, 215, and 252

[Docket DARS–2024–0028]

RIN 0750–AL55

Defense Federal Acquisition Regulation Supplement: DoD Cost or Pricing Data Requirements (DFARS Case 2022–D004)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement sections of the National Defense Authorization Acts for Fiscal Years 2018, 2021, and 2022 that update requirements for contractors to submit cost or pricing data.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before November 25, 2024, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2022–D004, using either of the following methods:

○ *Federal eRulemaking Portal:*
<https://www.regulations.gov>. Search for DFARS Case 2022–D004. Select “Comment” and follow the instructions to submit a comment. Please include “DFARS Case 2022–D004” on any attached documents.

○ *Email:* osd.dfars@mail.mil. Include DFARS Case 2022–D004 in the subject line of the message.

Comments received will generally be posted without change to <https://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check <https://www.regulations.gov>, approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Mr. Jon Snyder, telephone 703–945–5341.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement section 811(b) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91), section 814 of the NDAA for FY 2021 (Pub. L. 116–283), and section 804 of the NDAA for FY 2022 (Pub. L. 117–81). Section 811(b) of the NDAA for FY 2018 (10 U.S.C. 2306a(d), now 10

U.S.C. 3705(a)) requires offerors to submit data other than certified cost or pricing data upon contracting officer request. Section 814 of the NDAA for FY 2021 (10 U.S.C. 2306(a)(1), now 10 U.S.C. 3702(a)(2), (3), and (4)) establishes a \$2 million threshold for the Truthful Cost or Pricing Data statute (formerly Truth in Negotiations Act (TINA) and still referred to as TINA) requirements with respect to contract modifications, subcontracts, and modifications to subcontracts, respectively. Section 804 of the NDAA for FY 2022 augments the requirement at 10 U.S.C. 2306a(a)(6), now 10 U.S.C. 3702(f), for contracting officers to modify contracts to reflect the relevant TINA threshold.

II. Discussion and Analysis

TINA requires, with exceptions, that the Government obtain certified cost or pricing data for certain contract actions listed at Federal Acquisition Regulation (FAR) 15.403–4(a)(1), such as negotiated contracts, certain subcontracts, and certain contract modifications. Section 811(a) of the NDAA for FY 2018 increased the threshold for requesting certified cost or pricing data from \$750,000 to \$2 million for contracts entered into after June 30, 2018, but it left unchanged the \$750,000 threshold for prime contract modifications. The FAR was amended to reflect this change effective August 3, 2020.

Section 814 of the NDAA for FY 2021 established a uniform \$2 million threshold for TINA requirements with respect to DoD for contractual actions, including prime contract modifications, entered into after June 30, 2018. In implementing the change to the thresholds for prime contract modifications, this proposed rule includes a new contract clause at DFARS 252.215–70SS, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications, and its Alternate I. This clause is prescribed for use in lieu of FAR 52.215–21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, if the contracting officer anticipates, at the time of solicitation, that postaward submission of certified cost or pricing data or data other than certified cost or pricing data may possibly be required for modifications. Alternate I is used to specify a format for certified cost or pricing data other than the format required by FAR Table

15–2. Further, this proposed rule, at DFARS 215.403–4, requires use of the \$2 million threshold for submission of certified cost or pricing data in conjunction with relevant FAR contract clauses and solicitation provisions regardless of the date on which the contract was awarded.

Section 804 of the NDAA for FY 2022 augments the requirement at 10 U.S.C. 3702(f) for contracting officers, in connection with a contract entered into on or before June 30, 2018, to modify the contract to reflect the changed TINA threshold as necessary. In particular, section 804 requires that such modifications be executed “as soon as practicable.” DoD is proposing to change DFARS 215.403–4 accordingly, adding six clauses, prescribed at DFARS 214.201–7 and 215.408, specifically for use when modifying contracts in accordance with 10 U.S.C. 3702(f). The six clauses are as follows:

- 252.214–70QQ, Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications—Sealed Bidding.
- 252.214–70RR, Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications—Sealed Bidding.
- 252.215–70TT, Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
- 252.215–70UU, Alternate A, Subcontractor Certified Cost or Pricing Data.
- 252.215–70VV, Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications.
- 252.215–70WW, Alternate A, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications.

These new DFARS clauses are designed for use with the FAR clauses that are already in existing contracts. These six DFARS clauses replace the references to the TINA threshold in the FAR clauses with the current, relevant TINA threshold for DoD contracts.

Section 811(b) of the NDAA for FY 2018 requires offerors to submit data other than certified cost or pricing data upon contracting officer request. Accordingly, DoD proposes to change the solicitation provision at DFARS 252.215–7010, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data, and its Alternate I to require that, upon contracting officer request, the offeror shall submit data other than certified cost or pricing data to the extent necessary to determine the reasonableness of the price of the contract or subcontract. Similarly, the new clause at 252.215–70SS,

Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications, and its Alternate I reflect the same clarifying language.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Services and Commercial Products, Including Commercially Available Off-the-Shelf (COTS) Items

This rule proposes to amend the solicitation provision at DFARS 252.215–7010, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data, which already applies to solicitations using FAR part 12 procedures for the acquisition of commercial products and commercial services. The changes to the solicitation provision in this proposed rule, however, do not impose any new requirements on contracts at or below the SAT or for commercial services and commercial products, including COTS items. The provision will continue not to apply to acquisitions at or below the SAT but will continue to apply to acquisitions of commercial services and commercial products, including COTS items.

This proposed rule adds a new clause at DFARS 252.215–70SS, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications, and its Alternate I. The clause at DFARS 252.215–70SS is prescribed at DFARS 215.408(5)(ii) introductory text and (5)(ii)(A) and (B) for use in lieu of the clause at FAR 52.215–21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, if it is anticipated at the time of solicitation that postaward submission of certified cost or pricing data or data other than certified cost or pricing data may be required for prime contract modifications. Alternate I is prescribed when a format other than the FAR Table 15–2 format may be used for the certified cost or pricing data.

This proposed rule also includes new clauses at DFARS 252.214–70QQ, Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications—Sealed Bidding; 252.214–70RR, Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications—Sealed Bidding; 252.215–70TT, Alternate A, Price Reduction for Defective Certified Cost or

Pricing Data—Modifications; 252.215–70UU, Alternate A, Subcontractor Certified Cost or Pricing Data; 252.215–70VV, Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications; and 252.215–70WW, Alternate A, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications. These clauses are prescribed for use with the respective clauses at FAR 52.214–27, Price Reduction for Defective Certified Cost or Pricing Data—Modifications—Sealed Bidding; FAR 52.214–28, Subcontractor Certified Cost or Pricing Data—Modifications—Sealed Bidding; 52.215–11, Price Reduction for Defective Certified Cost or Pricing Data—Modifications; 52.215–12, Subcontractor Certified Cost or Pricing Data; and 52.215–13, Subcontractor Certified Cost or Pricing Data—Modifications; when, in accordance with 10 U.S.C. 3702(f), modifying a prime contract entered into before July 1, 2018. Therefore, these clauses are not appropriate for use in new FAR part 12 solicitations and contracts.

DoD does not intend to apply the proposed rule to contracts at or below the SAT. DoD does intend to apply the proposed rule to contracts for the acquisition of commercial services and commercial products, including COTS items.

A. Applicability to Contracts at or Below the Simplified Acquisition Threshold

The statute at 41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the simplified acquisition threshold. It is intended to limit the applicability of laws to such contracts or subcontracts. The statute at 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the Federal Acquisition Regulatory Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT, the law will apply to them. The Principal Director, Defense Pricing, Contracting, and Acquisition Policy (DPCAP), is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations. DoD does not intend to make that determination. Therefore, this proposed rule will not apply at or below the simplified acquisition threshold.

B. Applicability to Contracts for the Acquisition of Commercial Services and Commercial Products, Including COTS Items

The statute at 10 U.S.C. 3452 exempts contracts and subcontracts for the acquisition of commercial products, including COTS items, and commercial services from provisions of law enacted after October 13, 1994, unless the Under Secretary of Defense (Acquisition and Sustainment) (USD(A&S)) makes a written determination that it would not be in the best interest of DoD to exempt contracts for the procurement of commercial products and commercial services from the applicability of the provision or contract requirement, except for a provision of law that—

- Provides for criminal or civil penalties;
- Requires that certain articles be bought from American sources pursuant to 10 U.S.C. 4862 (previously 10 U.S.C. 2533c), or that strategic materials critical to national security be bought from American sources pursuant to 10 U.S.C. 4863 (previously 10 U.S.C. 2533b); or
- Specifically refers to 10 U.S.C. 3452 and states that it shall apply to contracts and subcontracts for the acquisition of commercial products (including COTS items) and commercial services.

The statutes implemented in this proposed rule do not impose criminal or civil penalties, do not require purchase pursuant to 10 U.S.C. 4862 or 4863, and do not refer to 10 U.S.C. 3452. Therefore, section 811(b) of the NDAA for FY 2018, section 814 of the NDAA for FY 2021, and section 804 of the NDAA for FY 2022 will not apply to the acquisition of commercial services or commercial products including COTS items unless a written determination is made. Due to delegations of authority, the Principal Director, DPCAP is the appropriate authority to make this determination. DoD intends to make that determination to apply these statutes to the acquisition of commercial products, including COTS items, and to the acquisition of commercial services.

C. Determination

DFARS 252.215–7010, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data, allows offerors to submit a written request for an exception from the requirement to submit certified cost or pricing data, by submitting specific information to support a commercial product or commercial service exception or an exception based on prices set by law or regulation. As this implies, DFARS 252.215–7010 is

presently prescribed for use in solicitations to include those using FAR part 12 procedures for the acquisition of commercial products and commercial services. This proposed rule does not include any changes to this prescription.

The requirements of section 811(b) of the NDAA for FY 2018, section 814 of the NDAA for FY 2021, and section 804 of the NDAA for FY 2022 should apply to the procurement of commercial products, including COTS items, and to the procurement of commercial services for the following reasons.

Implementation of these sections provides guidance concerning rendering of commercial product and commercial service determinations and the appropriate amount and type of other than certified cost or pricing information that contracting officers must require an offeror to submit in order to determine whether proposed prices for commercial products and commercial services are fair and reasonable. Exclusion of acquisitions of commercial products, including COTS items, and commercial services would greatly limit the impact of the statutory requirements and forestall the opportunity to clarify commercial product and commercial service documentation, pricing criteria, and requirements. For example, implementing section 811(b) of the NDAA for FY 2018 requires augmenting DFARS 252.215–7010, which presently applies to the acquisition of commercial products and commercial services. Section 804 of the NDAA for FY 2022 will be implemented in a proposed new DFARS clause, 252.215–70SS, that is applicable postaward in a manner analogous to the solicitation provision at DFARS 252.215–7010. The new clause at 252.215–70SS must similarly apply to the acquisition of commercial products and commercial services. In order to reflect congressional intent, section 814 of the NDAA for FY 2021 must apply to the acquisition of commercial products and commercial services as a consequence of 252.215–7010 applying to such acquisitions.

An exception for contracts for the acquisition of commercial items, including COTS items, would exclude the contracts intended to be covered by the law, thereby undermining the overarching public policy purpose of the law.

IV. Expected Impact of the Proposed Rule

By increasing the TINA threshold for contract modifications and subcontracts to match that of contracts entered into after June 30, 2018, this proposed rule,

when finalized, will benefit both the Government and the public. In particular, by implementing a uniform TINA threshold, this proposed rule will promote efficiency and reduce costs associated with administering contracts. This proposed rule requires contractors to provide data other than certified cost or pricing data when certified cost or pricing data is not required. Finally, this proposed rule provides Government contracting officers with the ability to obtain data other than certified cost or pricing data for contract modifications analogous to what they can obtain when issuing contracts. This data is critical for determining fair and reasonable prices when certified cost or pricing data is not required. Adding this language should expedite contract negotiations and award.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Regulatory Flexibility Act

DoD does not expect this proposed rule, when finalized, to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the proposed rule does not add to existing requirements for the submission of other than certified cost or pricing data for the purpose of determining the reasonableness of proposed prices; rather, the proposed rule decreases the number of contracts and subcontracts subject to TINA. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

DoD is proposing to amend the DFARS to implement the following: section 811(b) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91), section 814 of the NDAA for FY 2021 (Pub. L. 116–283), and section 804 of the NDAA for FY 2022 (Pub. L. 117–81). Section 811(b) of the NDAA for FY 2018 (10

U.S.C. 2306a(d), now 10 U.S.C. 3705(a)) requires offerors to submit data other than certified cost or pricing data upon contracting officer request. Section 814 of the NDAA for FY 2021 (10 U.S.C. 2306(a)(1), now 10 U.S.C. 3702(a)(2), (3), and (4)) establishes a \$2 million threshold for the Truthful Cost or Pricing Data (Truth in Negotiations) statute (referred to as TINA) requirements with respect to contract modifications, subcontracts, modifications to subcontracts. TINA requires, with notable exceptions, contractors to submit cost or pricing data and to certify the accuracy of the data, for the award of negotiated contracts exceeding the \$2 million threshold. Section 804 of the NDAA for FY 2022 augments the requirement at 10 U.S.C. 2306a(a)(6) (now 10 U.S.C. 3702(f)) for contracting officers to modify contracts to reflect the relevant TINA threshold. Section 804 requires such modifications to be executed “as soon as practicable.”

The objective of this proposed rule is to propose amendments to the DFARS to implement the statutory changes described above. The legal basis for the proposed rule is section 811(b) of the NDAA for FY 2018, section 814 of the NDAA for FY 2021, and section 804 of the NDAA for FY 2022.

Data was obtained from the Federal Procurement Data System for new awards valued over \$2 million in FY 2019, FY 2020, and FY 2021. DoD awarded an average of 10,593 contracts per year during FY 2019 through FY 2021. Of those contracts, an average of approximately 5,567 contracts were awarded to 3,659 unique small entities per year. By increasing the TINA threshold for contract modifications and subcontracts, this proposed rule will benefit small businesses by reducing the overall number of contracts to which TINA requirements apply.

The proposed rule imposes new reporting, recordkeeping, or compliance requirements via proposed DFARS clause 252.215–70SS, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known alternatives that would accomplish the stated objectives of the applicable statutes.

DoD invites comments from small business concerns and other interested parties on the expected impact of this proposed rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected

by this proposed rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2022–D004), in correspondence.

VII. Paperwork Reduction Act

This proposed rule contains information collection requirements that require the approval of the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. chapter 35). Accordingly, DoD has submitted a request for approval of a revised information collection requirement concerning OMB Control Number 0704–0574, titled “Defense Federal Acquisition Regulation Supplement (DFARS) Part 215; Only One Offer and Related Clauses at 252.215,” to OMB.

A. Estimate of Public Burden

Public reporting burden for this collection of information is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden estimated as follows:

Respondents: 1,247.

Total annual responses: 1,435.

Total annual burden hours: 50,190.

B. Request for Comments Regarding Paperwork Burden

Written comments and recommendations on the proposed information collection, including suggestions for reducing this burden, should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov> or by email to osd.dfars@mail.mil. Comments can be received up to 60 days after the date of this notice.

Public comments are particularly invited on: whether this 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 this 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.

To obtain a copy of the supporting statement and associated collection instruments, please email osd.dfars@mail.mil. Include DFARS Case 2022–D004 in the subject line of the message.

List of Subjects in 48 CFR Parts 212, 214, 215, and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System proposes to amend 48 CFR parts 212, 214, 215, and 252 amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 214, 215, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 2. Amend section 212.301 by revising paragraph (f)(vi)(E) introductory text and adding paragraph (f)(vi)(G) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

(f) * * *
(vi) * * *

(E) Use the provision 252.215–7010, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data, as prescribed at 215.408(5)(i) to comply with section 831 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239) and 10 U.S.C. 3702(a), 3703(d) and (e), and 3705(a).

* * * * *

(G) Use the clause at 252.215–70SS, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications, as prescribed at 215.408(5)(ii) to comply with section 831 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239) and 10 U.S.C. 3702(a), 3703(d) and (e), and 3705(a).

* * * * *

PART 214—SEALED BIDDING

■ 3. Revise section 214.201–6 to read as follows:

214.201–6 Solicitation provisions.

Use the provisions at 252.215–7007, Notice of Intent to Resolicit, and 252.215–7008, Only One Offer, as prescribed at 215.371–6 and 215.408(3), respectively.

■ 4. Add section 214.201–7 to read as follows:

214.201–7 Contract clauses.

(b)(1) When modifying a contract entered into before July 1, 2018, in accordance with 215.403–4(a)(3), use the clause at FAR 52.214–27, Price Reduction for Defective Certified Cost or Pricing Data—Modifications—Sealed Bidding, with 252.214–70QQ, Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications—Sealed Bidding.

(c)(1)(ii) When modifying a contract entered into before July 1, 2018, in accordance with 215.403–4(a)(3), use the clause at FAR 52.214–28, Subcontractor Certified Cost or Pricing Data—Modifications—Sealed Bidding, with 252.214–70RR, Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications—Sealed Bidding. Do not use alternate I of the clause at FAR 52.214–28.

PART 215—CONTRACTING BY NEGOTIATION

■ 5. Add section 215.403–4 to read as follows:

215.403–4 Requiring certified cost or pricing data (10 U.S.C. chapter 271 and 41 U.S.C. chapter 35).

(a)(1) Notwithstanding FAR 15.403–4(a)(1), the \$2 million threshold for obtaining certified cost or pricing data applies to contract modifications, subcontracts, and subcontract modifications, regardless of when the prime contract was awarded.

(3) For a contract entered into before July 1, 2018, the contracting officer shall modify the contract as soon as practicable, without requiring consideration, to reflect the threshold at paragraph (a)(1) for obtaining certified cost or pricing data on contract modifications and subcontracts entered into on or after July 1, 2018 (10 U.S.C. 3702(f)). See 214.201–7 and 215.408.

■ 6. Amend section 215.408—

■ a. By redesignating paragraphs (5)(ii) and (iii) as paragraphs (5)(iii) and (iv); and
■ b. By adding a new paragraph (5)(ii) and paragraph (9).

The additions read as follows:

215.408 Solicitation provisions and contract clauses.

* * * * *

(5) * * *

(ii) Use the basic or alternate of the clause at 252.215–70SS, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications, in lieu of the clause at FAR 52.215–21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—

Modifications, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, if it is reasonably certain that certified cost or pricing data or data other than certified cost or pricing data will be required for modifications.

(A) Use the basic clause when submission of certified cost or pricing data is required to be in the FAR Table 15–2 format.

(B) Use the alternate I clause to specify a format for certified cost or pricing data other than the format required by FAR Table 15–2.

* * * * *

(9) When modifying a prime contract entered into before July 1, 2018, in accordance with 215.403–4(a)(3)—

(i) Use the clause at FAR 52.215–11, Price Reduction for Defective Certified Cost or Pricing Data—Modifications, with 252.215–70TT, Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications.

(ii)(A) Use the clause at FAR 52.215–12, Subcontractor Certified Cost or Pricing Data, with 252.215–70UU, Alternate A, Subcontractor Certified Cost or Pricing Data.

(B) Do not use alternate I of the clause at FAR 52.215–12.

(iii)(A) Use the clause at FAR 52.215–13, Subcontractor Certified Cost or Pricing Data—Modifications, with 252.215–70VV, Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications.

(B) Do not use alternate I of the clause at FAR 52.215–13.

(iv) Use the clause at 52.215–21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications, with 252.215–70WW, Alternate A, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 7. Add section 252.214–70QQ to read as follows:

252.214–70QQ Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications—Sealed Bidding.

As prescribed in 214.201–7(b)(1), use the following clause:

Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications—Sealed Bidding (Date)

Substitute “215.403–4(a)(1) of the Defense Federal Acquisition Regulation Supplement” for references to 15.403–4(a)(1) of the Federal Acquisition Regulation wherever they appear in the clause at 52.214–27, Price Reduction for Defective Certified Cost or Pricing Data—Modifications—Sealed Bidding.

(End of clause)

■ 8. Add section 252.214–70RR to read as follows:

252.214–70RR Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications—Sealed Bidding.

As prescribed in 214.201–7(c)(1)(ii), use the following clause:

Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications—Sealed Bidding (Date)

Substitute “215.403–4(a)(1) of the Defense Federal Acquisition Regulation Supplement” for references to 15.403–4(a)(1) of the Federal Acquisition Regulation wherever they appear in the clause at 52.214–28, Subcontractor Certified Cost or Pricing Data—Modifications—Sealed Bidding.

(End of clause)

■ 9. Amend section 252.215–7010—

■ a. By removing the provision date of “(MAY 2024)” and adding “(DATE)” in its place;

■ b. By revising paragraph (b)(1)(ii)(C);

■ c. In paragraph (b)(1)(ii)(D) by removing “items” and “the DoD” and adding “products or services” and “DoD” in their places, respectively;

■ d. In paragraphs (b)(1)(ii)(E) and (F) by removing “items” and adding “products or services” in its place;

■ e. By revising paragraph (c)(3);

■ f. By redesignating paragraphs (d)(1) through (5) as paragraphs (d)(2) through (6);

■ g. By adding a new paragraph (d)(1);

■ h. In newly redesignated paragraph (d)(5) by removing “FAR 15.403–3” and adding “this paragraph (d)” in its place;

■ i. In paragraph (e)(1) by removing “FAR 15.403–4” and adding “DFARS 215.403–4(a)(1)” in its place; and

■ j. In Alternate I—

■ i. By removing the provision date of “(MAY 2024)” and adding “(DATE)” in its place;

■ ii. By revising paragraph (b)(1)(ii)(C);

■ iii. In paragraph (b)(1)(ii)(D) by removing “items” and “the DoD” and adding “products or services” and “DoD” in their places, respectively;

■ iv. In paragraph (b)(1)(ii)(E) by removing “items” and adding “products or services” in its place;

■ v. By revising paragraphs (b)(1)(ii)(F) and (c)(3);

■ vi. By redesignating paragraphs (d)(1) through (6) as paragraphs (d)(2) through (7);

■ vii. By adding a new paragraph (d)(1);

■ viii. By revising newly redesignated paragraph (d)(6); and

■ ix. In paragraph (e)(1) by removing “FAR 15.403–4” and adding “DFARS 215.403–4(a)(1)” in its place.

The revisions and additions read as follows:

252.215–7010 Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(C) For products or services priced based on a catalog—

(1) A copy of or identification of the Offeror’s current catalog showing the price for that product or service; and

(2) If the catalog pricing provided with this proposal is not supported by all relevant sales data, a detailed description of differences or inconsistencies between or among the relevant sales data, the proposed price, and the catalog price (including any related discounts, refunds, rebates, offsets, or other adjustments);

* * * * *

(c) * * *

(3) The Offeror is responsible for determining whether a subcontractor qualifies for an exception from the requirement for submission of certified cost or pricing data on the basis of adequate price competition in accordance with FAR 15.403–1(c)(1)(i).

(d) * * *

(1) When certified cost or pricing data are not required to be submitted under this provision, the Offeror shall submit data to the extent necessary to determine the reasonableness of the price of the contract or subcontract, when requested by the Contracting Officer.

* * * * *

Alternate I. * * *

(b) * * *

(1) * * *

(ii) * * *

(C) For products or services priced based on a catalog—

(1) A copy of or identification of the Offeror’s current catalog showing the price for that product or service; and

(2) If the catalog pricing provided with this proposal is not supported by all relevant sales data, a detailed description of differences or inconsistencies between or among the relevant sales data, the proposed price, and the catalog price (including any

related discounts, refunds, rebates, offsets, or other adjustments);

* * * * *

(F) For products or services provided by nontraditional defense contractors, a statement that the entity is not currently performing and has not performed, for at least the 1-year period preceding the solicitation of sources by DoD for the procurement or transaction, any contract or subcontract for DoD that is subject to full coverage under the cost accounting standards prescribed pursuant to 41 U.S.C. 1502 and the regulations implementing such section.

* * * * *

(c) * * *

(3) The Offeror is responsible for determining whether a subcontractor qualifies for an exception from the requirement for submission of certified cost or pricing data on the basis of adequate price competition in accordance with FAR 15.403–1(c)(1)(i).

(d) * * *

(1) When certified cost or pricing data are not required to be submitted under this provision, the Offeror shall submit data to the extent necessary to determine the reasonableness of the price of the contract or subcontract, when requested by the Contracting Officer.

* * * * *

(5) Within 10 days of a written request from the Contracting Officer for additional information to permit an adequate evaluation of the proposed price in accordance with this paragraph (d), the Offeror shall provide either the requested information, or a written explanation for the inability to fully comply.

* * * * *

■ 10. Add section 252.215–70SS to read as follows:

252.215–70SS Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications.

As prescribed in 215.408(5)(ii) and (5)(ii)(A), use the following basic clause:

Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications—Basic (DATE)

(a) *Definitions.* As used in this clause—

Market prices means current prices that are established in the course of ordinary trade between buyers and sellers free to bargain and that can be substantiated through competition or from sources independent of the offeror, contractor, or subcontractor.

Non-Government sales means sales of the supplies or services to non-Governmental entities for purposes other than governmental purposes.

Relevant sales data means information provided by an offeror, contractor, or subcontractor on sales of the same or similar items that can be used to establish price reasonableness taking into consideration the age, volume, and nature of the transactions (including any related discounts, refunds, rebates, offsets, or other adjustments).

Sufficient non-Government sales means relevant sales data that reflects market pricing and contains enough information to make adjustments covered by Federal Acquisition Regulation (FAR) 15.404–1(b)(2)(ii)(B).

Uncertified cost data means the subset of “data other than certified cost or pricing data” (see FAR 2.101) that relates to cost.

(b) *Exceptions from certified cost or pricing data.*

(1) In lieu of submitting certified cost or pricing data for modifications under this contract, for price adjustments expected to exceed the threshold set forth in Defense Federal Acquisition Regulation Supplement (DFARS) 215.403–4(a)(1), the Contractor may submit a written request for exception by submitting the information described in paragraphs (b)(1)(i) and (ii) of this clause. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted and whether the price is fair and reasonable.

(i) *Exception for prices set by law or regulation—Identification of the law or regulation establishing the prices offered.* If the prices are controlled under law by periodic rulings, reviews, or similar actions of a governmental body, provide a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) *Commercial product and commercial service exception.* For a commercial product or commercial service exception, the Contractor shall submit, at a minimum, information that is adequate for evaluating the reasonableness of the price for this modification, including prices at which the same or similar products or services have been sold in the commercial market. The Contractor may provide information establishing that the proposed modification would not change the existing contract or subcontract from a contract or subcontract for a commercial product or commercial service to one for other than a commercial product or service. Such information shall include—

(A) For products or services previously determined to be commercial, the contract number and military department, defense agency, or other DoD component that rendered such determination and, if available, a Government point of contact;

(B) For products or services priced based on a catalog—

(1) A copy of or identification of the Contractor’s current catalog showing the price for that product or service; and

(2) If the catalog pricing provided with this proposal is not supported by all relevant sales data, a detailed description of differences or inconsistencies between or among the relevant sales data, the proposed price, and the catalog price, including any related discounts, refunds, rebates, offsets, or other adjustments;

(C) For products or services priced based on market pricing, a description of the nature of the commercial market, the methodology used to establish a market price, and all relevant sales data. The description shall be adequate to permit DoD to verify the accuracy of the description;

(D) For products or services included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule products or services; or

(E) For products or services provided by nontraditional defense contractors, a statement that the entity is not currently performing and has not performed, for at least the 1-year period preceding the solicitation of sources by DoD for the procurement, any contract or subcontract for DoD that is subject to full coverage under the cost accounting standards prescribed pursuant to 41 U.S.C. 1502 and the regulations implementing such section.

(2) The Contractor grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this clause, and to determine the reasonableness of price.

(c) *Requirements for certified cost or pricing data.* If the Contractor is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The Contractor shall prepare and submit certified cost or pricing data and supporting attachments in accordance with the instructions contained in Table 15–2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15–2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and replace this clause with Alternate I of 252.215–70SS.

(2) As soon as practicable after agreement on price, but before award of the modification, the Contractor shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406–2.

(3) The Contractor is responsible for determining whether a subcontractor qualifies for an exception from the requirement for submission of certified cost or pricing data on the basis of adequate price competition in accordance with FAR 15.403–1(c)(1)(i).

(d) *Requirements for data other than certified cost or pricing data.*

(1) When certified cost or pricing data are not required to be submitted under this clause for a contract or subcontract, the Contractor shall submit data other than certified cost or pricing data to the extent necessary to determine the reasonableness of the price of the contract or subcontract when requested by the Contracting Officer.

(2) Data other than certified cost or pricing data submitted in accordance with this clause shall include the minimum information necessary to permit a determination that the proposed price is fair and reasonable, to include the requirements in DFARS 215.402(a)(i) and 215.404–1(b).

(3) In cases in which uncertified cost data is required, the information shall be provided in the form in which it is regularly maintained by the Contractor, subcontractor, or prospective subcontractor in its business operations.

(4) Within 10 days of a written request from the Contracting Officer for additional information to permit an adequate evaluation of the proposed price in accordance with this paragraph, the Contractor shall provide either the requested information or a written explanation for the inability to fully comply.

(e) *Subcontract price evaluation.*

(1) Contractors shall obtain from subcontractors the minimum information necessary to support a determination of price reasonableness, as described in FAR part 15 and DFARS part 215.

(2) No cost data may be required from a current or prospective subcontractor in any case in which there are sufficient non-Government sales of the same item to establish reasonableness of price.

(3) If the Contractor relies on relevant sales data for similar items to determine the price is reasonable, the Contractor shall obtain only that technical information necessary to—

(i) Support the conclusion that items are technically similar; and

(ii) Explain any technical differences that account for variances between the proposed prices and the sales data presented.

(f) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (f), in subcontracts exceeding the simplified acquisition threshold defined in FAR part 2. The Contractor shall require subcontractors and prospective subcontractors to adhere to the requirements of—

(1) Paragraphs (c) and (d) of this clause for subcontracts above the threshold for submission of certified cost or pricing data in DFARS 215.403–4(a)(1); and

(2) Paragraph (d) of this clause for subcontracts exceeding the simplified acquisition threshold defined in FAR part 2. (End of clause)

Alternate I. As prescribed in 215.408(5)(ii) and (5)(ii)(B), use the following clause, which includes a different paragraph (c)(1) than the basic clause and amends paragraph (d) by redesignating paragraph (d)(4) of the basic clause as (d)(5) and adding a new paragraph (d)(4).

Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications—Alternate I (DATE)

(a) *Definitions.* As used in this clause—

Market prices means current prices that are established in the course of ordinary trade between buyers and sellers free to bargain and that can be substantiated through competition or from sources independent of the offeror, contractor, or subcontractor.

Non-Government sales means sales of the supplies or services to non-Governmental entities for purposes other than governmental purposes.

Relevant sales data means information provided by an offeror, contractor, or subcontractor on sales of the same or similar

items that can be used to establish price reasonableness taking into consideration the age, volume, and nature of the transactions (including any related discounts, refunds, rebates, offsets, or other adjustments).

Sufficient non-Government sales means relevant sales data that reflects market pricing and contains enough information to make adjustments covered by Federal Acquisition Regulation (FAR) 15.404–1(b)(2)(ii)(B).

Uncertified cost data means the subset of “data other than certified cost or pricing data” (see FAR 2.101) that relates to cost.

(b) *Exceptions from certified cost or pricing data.*

(1) In lieu of submitting certified cost or pricing data for modifications under this contract, for price adjustments expected to exceed the threshold set forth in Defense Federal Acquisition Regulation Supplement (DFARS) 215.403–4(a)(1), the Contractor may submit a written request for exception by submitting the information described in paragraphs (b)(1)(i) and (ii) of this clause. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted and whether the price is fair and reasonable.

(i) *Exception for prices set by law or regulation—Identification of the law or regulation establishing the prices offered.* If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, provide a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) *Commercial product and commercial service exception.* For a commercial product or commercial service exception, the Contractor shall submit, at a minimum, information that is adequate for evaluating the reasonableness of the price for this modification, including prices at which the same or similar products or services have been sold in the commercial market. The Contractor may provide information establishing that the proposed modification would not change the existing contract or subcontract from a contract or subcontract for a commercial product or commercial service to one for other than a commercial product or service. Such information shall include—

(A) For products or services previously determined to be commercial, the contract number and military department, defense agency, or other DoD component that rendered such determination and, if available, a Government point of contact;

(B) For products or services priced based on a catalog—

(1) A copy of or identification of the Contractor’s current catalog showing the price for that product or service; and

(2) If the catalog pricing provided with this proposal is not supported by all relevant sales data, a detailed description of differences or inconsistencies between or among the relevant sales data, the proposed price, and the catalog price, including any related discounts, refunds, rebates, offsets, or other adjustments;

(C) For products or services priced based on market pricing, a description of the nature

of the commercial market, the methodology used to establish a market price, and all relevant sales data. The description shall be adequate to permit DoD to verify the accuracy of the description;

(D) For products or services included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule products or services; or

(E) For products or services provided by nontraditional defense contractors, a statement that the entity is not currently performing and has not performed, for at least the 1-year period preceding the solicitation of sources by DoD for the procurement, any contract or subcontract for DoD that is subject to full coverage under the cost accounting standards prescribed pursuant to 41 U.S.C. 1502 and the regulations implementing such section.

(2) The Contractor grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this clause, and to determine the reasonableness of price.

(c) *Requirements for certified cost or pricing data.* If the Contractor is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The Contractor shall submit certified cost or pricing data and supporting attachments in the following format: *[Contracting officer insert description of the data and format that are required, and include access to records necessary to permit an adequate evaluation of the proposed price in accordance with FAR 15.408, Table 15–2, Note 2. The Contracting Officer shall insert the description at the time of issuing the solicitation or specify that the format regularly maintained by the Contractor or current or prospective subcontractor in its business operations will be acceptable. The Contracting Officer may amend the description as the result of negotiations.]*

(2) As soon as practicable after agreement on price, but before award of the modification, the Contractor shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406–2.

(3) The Contractor is responsible for determining whether a subcontractor qualifies for an exception from the requirement for submission of certified cost or pricing data on the basis of adequate price competition in accordance with FAR 15.403–1(c)(1)(i).

(d) *Requirements for data other than certified cost or pricing data.*

(1) When certified cost or pricing data are not required to be submitted under this clause for a contract or subcontract, the Contractor shall submit data other than certified cost or pricing data to the extent necessary to determine the reasonableness of the price of the contract or subcontract when requested by the Contracting Officer.

(2) Data other than certified cost or pricing data submitted in accordance with this clause shall include the minimum information necessary to permit a determination that the proposed price is fair

and reasonable, to include the requirements in DFARS 215.402(a)(i) and 215.404–1(b).

(3) In cases in which uncertified cost data is required, the information shall be provided in the form in which it is regularly maintained by the Contractor, subcontractor, or prospective subcontractor in its business operations.

(4) The Contractor shall provide information described as follows: *[Insert description of the data and the format that are required upon request, including access to records necessary to permit an adequate evaluation of the proposed price in accordance with FAR 15.403–3].*

(5) Within 10 days of a written request from the Contracting Officer for additional information to permit an adequate evaluation of the proposed price in accordance with this paragraph, the Contractor shall provide either the requested information or a written explanation for the inability to fully comply.

(e) *Subcontract price evaluation.*

(1) The Contractor shall obtain from subcontractors the information necessary to support a determination of price reasonableness, as described in FAR part 15 and DFARS part 215.

(2) No cost data may be required from a current or prospective subcontractor in any case in which there are sufficient non-Government sales of the same item to establish reasonableness of price.

(3) If the Contractor relies on relevant sales data for similar items to determine the price is reasonable, the Contractor shall obtain only that technical information necessary to—

(i) Support the conclusion that items are technically similar; and

(ii) Explain any technical differences that account for variances between the proposed prices and the sales data presented.

(f) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (f), in subcontracts exceeding the simplified acquisition threshold defined in FAR part 2. The Contractor shall require subcontractors and prospective subcontractors to adhere to the requirements of—

(1) Paragraphs (c) and (d) of this clause for subcontracts above the threshold for submission of certified cost or pricing data in DFARS 215.403–4(a)(1); and

(2) Paragraph (d) of this clause for subcontracts exceeding the simplified acquisition threshold defined in FAR part 2.

(End of clause)

■ 11. Add sections 252.215–70TT, 252.215–70UU, 252.215–70VV, and 252.215–70WW to read as follows:

* * * * *

Sec.

252.215–70TT Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications.

252.215–70UU Alternate A, Subcontractor Certified Cost or Pricing Data.

252.215–70VV Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications.

252.215–70WW Alternate A, Requirements for Certified Cost or Pricing Data and

Data Other Than Certified Cost or Pricing Data—Modifications.

* * * * *

252.215–70TT Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications.

As prescribed in 215.408(9)(i), use the following clause:

Alternate A, Price Reduction for Defective Certified Cost or Pricing Data—Modifications (DATE)

Substitute “215.403–4(a)(1) of the Defense Federal Acquisition Regulation Supplement” for references to 15.403–4(a)(1) of the Federal Acquisition Regulation wherever they appear in the clause at 52.215–11, Price Reduction for Defective Certified Cost or Pricing Data—Modifications.

(End of clause)

252.215–70UU Alternate A, Subcontractor Certified Cost or Pricing Data.

As prescribed in 215.408(9)(ii), use the following clause:

Alternate A, Subcontractor Certified Cost or Pricing Data (DATE)

Substitute “215.403–4(a)(1) of the Defense Federal Acquisition Regulation Supplement” for references to 15.403–4(a)(1) of the Federal Acquisition Regulation wherever they appear in the clause at 52.215–12, Subcontractor Certified Cost or Pricing Data.

(End of clause)

252.215–70VV Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications.

As prescribed in 215.408(9)(iii), use the following clause:

Alternate A, Subcontractor Certified Cost or Pricing Data—Modifications (DATE)

Substitute “215.403–4(a)(1) of the Defense Federal Acquisition Regulation Supplement” for references to 15.403–4(a)(1) of the Federal Acquisition Regulation wherever they appear in the clause at 52.215–13, Subcontractor Certified Cost or Pricing Data—Modifications.

(End of clause)

252.215–70WW Alternate A, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications.

As prescribed in 215.408(9)(iv), use the following clause:

Alternate A, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications (DATE)

Substitute “215.403–4(a)(1) of the Defense Federal Acquisition Regulation Supplement” for references to 15.403–4(a)(1) of the Federal Acquisition Regulation wherever they appear in the clause at 52.215–21, Requirements for

Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications.

(End of clause)

[FR Doc. 2024–21098 Filed 9–25–24; 8:45 am]

BILLING CODE 6820–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 209, 212, 237, and 252

[Docket DARS–2024–0029]

RIN 0750–AM04

Defense Federal Acquisition Regulation Supplement: Preventing Conflicts of Interest for Certain Consulting Services (DFARS Case 2024–D007)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2024 that prohibits contracting officers from awarding contracts assigned certain North American Industry Classification System codes to offerors that hold contracts that involve consulting services with certain covered foreign entities.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before November 25, 2024, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2024–D007, using either of the following methods:

○ *Federal eRulemaking Portal:* <https://www.regulations.gov>. Search for DFARS Case 2024–D007. Select “Comment” and follow the instructions to submit a comment. Please include “DFARS Case 2024–D007” on any attached documents.

○ *Email:* osd.dfars@mail.mil. Include DFARS Case 2024–D007 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. To confirm receipt of your comment(s), please check <https://www.regulations.gov>, approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Mr. Jon Snyder, telephone 703–945–5341.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement section 812 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2024 (Pub. L. 118–31). Section 812 prohibits contracting officers from awarding contracts assigned a North American Industry Classification System (NAICS) code beginning with 5416 to offerors who hold contracts that involve consulting services with certain covered foreign entities. NAICS codes beginning with 5416 are for management, scientific, and technical consulting services. Section 812 allows an offeror to submit a conflict-of-interest mitigation plan and allows the prohibition to be waived under certain circumstances.

II. Discussion and Analysis

This proposed rule includes a new section 209.57X, Conflicts of Interest in Certain Consulting Services, to implement section 812 of the NDAA for FY 2024. This new section 209.57X provides contracting officers the scope, definitions, prohibition, and waiver procedures for conflicts of interest in consulting services. DFARS 209.57X(c) prohibits contracting officers from awarding contracts assigned a NAICS code beginning with 5416 to an offeror that holds a contract for consulting services with one or more covered foreign entities if the offeror does not have an approved conflict-of-interest mitigation plan. DFARS 209.57X(b) contains the definitions of “consulting services”, “contract oversight entity”, “covered contract”, and “covered foreign entity”. The proposed rule also includes DFARS 209.503–70, which specifies the waiver authority for the prohibition at 209.57X(c).

A new solicitation provision is proposed at DFARS 252.209–70XX, Prohibition Relating to Conflicts of Interest in Consulting Services—Certification, for use in solicitations assigned a NAICS code beginning with 5416 that involve consulting services, including solicitations using Federal Acquisition Regulation (FAR) part 12 procedures for the acquisition of commercial services. DFARS 252.209–70XX requires an offeror to certify whether or not the offeror, its subsidiaries, or its affiliates hold a contract for consulting services with one or more covered foreign entities. If the offeror cannot certify to this, the offeror may contact the contracting officer for guidance on submitting an existing

conflict-of-interest mitigation plan. If such a plan is submitted and approved, the provision specifies that the plan will be incorporated into any resulting contract awarded to the offeror. The new solicitation provision is prescribed at 209.57X(e).

The new solicitation provision is proposed to be added to the list of provisions and clauses for use in solicitations and contracts for commercial products and commercial services at DFARS 212.301.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This proposed rule proposes a new provision at DFARS 252.209–70XX, Prohibition Relating to Conflicts of Interest in Consulting Services—Certification, to implement the requirements of section 812 of the NDAA for FY 2024. The provision at DFARS 252.209–70XX is prescribed at DFARS 209.57X(e) for use in solicitations assigned a NAICS code beginning with 5416 that involve consulting services, including solicitations using FAR part 12 procedures for the acquisition of commercial services. DoD does intend to apply the proposed rule to contracts at or below the SAT and for the acquisition of commercial services. DoD does not intend to apply the proposed rule to contracts for the acquisition of commercial products, including COTS items.

A. Applicability to Contracts at or Below the Simplified Acquisition Threshold

The statute at 41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the simplified acquisition threshold. It is intended to limit the applicability of laws to such contracts or subcontracts. The statute at 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the Federal Acquisition Regulatory Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT, the law will apply to them. The Principal Director, Defense Pricing, Contracting, and Acquisition Policy (DPCAP), is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the Federal Acquisition Regulation system of regulations. DoD does intend to make that determination. Therefore, this

proposed rule will apply at or below the simplified acquisition threshold.

B. Applicability to Contracts for the Acquisition of Commercial Products Including COTS Items and for the Acquisition of Commercial Services

The statute at 10 U.S.C. 3452 exempts contracts and subcontracts for the acquisition of commercial products including COTS items, and commercial services from provisions of law enacted after October 13, 1994, unless the Under Secretary of Defense (Acquisition and Sustainment) (USD(A&S)) makes a written determination that it would not be in the best interest of DoD to exempt contracts for the procurement of commercial products and commercial services from the applicability of the provision or contract requirement, except for a provision of law that—

- Provides for criminal or civil penalties;
- Requires that certain articles be bought from American sources pursuant to 10 U.S.C. 4862 (previously 10 U.S.C. 2533c), or that strategic materials critical to national security be bought from American sources pursuant to 10 U.S.C. 4863 (previously 10 U.S.C. 2533b); or
- Specifically refers to 10 U.S.C. 3452 and states that it shall apply to contracts and subcontracts for the acquisition of commercial products (including COTS items) and commercial services.

The statute implemented in this proposed rule does not impose criminal or civil penalties, does not require purchase pursuant to 10 U.S.C. 4862 or 4863, and does not refer to 10 U.S.C. 3452. Therefore, section 812 of the NDAA for FY 2024 will not apply to the acquisition of commercial services or commercial products including COTS items unless a written determination is made. Due to delegations of authority, the Principal Director, DPCAP is the appropriate authority to make this determination.

DoD intends to make that determination to apply this statute to the acquisition of commercial services. DoD does not intend to make that determination to apply this statute to the acquisition of commercial products including COTS items. Therefore, this proposed rule will apply to the acquisition of commercial services but will not apply to the acquisition of commercial products including COTS items.

C. Determinations

Given that the requirements of section 812 of the NDAA for FY 2024 were enacted to ensure the integrity and security of contracted consulting

services, it is in the best interest of the Federal Government to apply the statute to contracts valued at or below the SAT and for the acquisition of commercial services, as defined at Federal Acquisition Regulation 2.101.

Acquisitions below the SAT represent 42 percent of the consulting services contracts awarded in the last three fiscal years. Therefore, excluding these contracts would result in a significant national security risk.

Consulting services are commercial services, as defined at FAR 2.101. Therefore, an exception for contracts for the acquisition of commercial services would exclude the contracts intended to be covered by the law, thereby undermining the overarching purpose of the law.

IV. Expected Impact of the Rule

This proposed rule, when finalized, will prohibit contracting officers from awarding contracts, assigned a NAICS code beginning with 5416, to offerors who hold contracts that involve consulting services with covered foreign entities. NAICS codes beginning with 5416 are for management, scientific, and technical consulting services.

Offerors responding to solicitations assigned those NAICS codes will be required to certify whether or not they hold contracts that involve consulting services with one or more covered foreign entities and whether they maintain a conflict-of-interest mitigation plan. If an offeror certifies that they do hold such a contract, the offeror may consult with the contracting officer and submit a conflict-of-interest mitigation plan that is auditable by a contract oversight entity. If the offeror's plan is approved, the contracting officer will incorporate the plan into the resulting contract. If the offeror does not submit a conflict-of-interest mitigation plan, the contracting officer may determine the award is in the best interests of the United States with appropriate approval. In addition, the agency will be required to submit to Congress any use of such waiver authority.

DoD expects this proposed rule, when finalized, to prevent adversaries from accessing sensitive information that may cause harm to the United States.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Regulatory Flexibility Act

DoD does not expect this proposed rule, when finalized, to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because this proposed rule primarily impacts offerors that hold contracts with certain covered foreign entities. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This proposed rule is required to implement section 812 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2024 (Pub. L. 118–31). Section 812 prohibits contracting officers from awarding contracts, assigned a North American Industry Classification System (NAICS) code beginning with 5416, to an offeror that holds a contract for consulting services with one or more covered foreign entities. NAICS codes beginning with 5416 are for management, scientific, and technical consulting services.

The objective of this proposed rule is to implement section 812 of the NDAA for FY 2024, which is the legal basis for this proposed rule.

According to data obtained from the Procurement Integrated Enterprise Environment in the last three fiscal years, DoD awarded contracts with NAICS codes starting with 5416 to an average of 864 unique small entities per year. However, DoD cannot determine how many of those contracts awarded to small entities involve potential conflicts of interest.

This proposed rule does impose new reporting, recordkeeping, or other compliance requirements for small entities. The new solicitation provision at DFARS 252.209–70XX, Notice of Prohibition Relating to Conflicts of Interest in Consulting Services—Certification, requires offerors to certify whether they or their subsidiaries or affiliates hold a contract for consulting services with one or more covered entities and whether they maintain a conflict-of-interest mitigation plan that meets certain criteria listed in the solicitation provision.

This proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known alternatives that would accomplish the stated objectives of the applicable statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this proposed rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this proposed rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2024–D007), in correspondence.

VII. Paperwork Reduction Act

This proposed rule contains information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35). Accordingly, DoD has submitted a request for approval of a new information collection requirement concerning DFARS Case 2024–D007, Preventing Conflicts of Interest for Certain Consulting Services, to the Office of Management and Budget.

A. Estimate of Public Burden

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows:

1. Certification

Respondents: 5,307.
Number of annual responses: 5,307.
Annual burden hours: 5,307.

2. Conflict-of-Interest Mitigation Plan

Respondents: 114.
Number of annual responses: 177.
Annual burden hours: 144.

3. Total Public Burden

Respondents: 5,307.
Number of annual responses: 5,484.
Annual burden hours: 5,484.

B. Request for Comments Regarding Paperwork Burden

Written comments and recommendations on the proposed information collection, including suggestions for reducing this burden, should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov> or by email to osd.dfars@mail.mil. Comments can be received up to 60 days after the date of this document.

Public comments are particularly invited on: whether this 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 this 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.

To obtain a copy of the supporting statement and associated collection instruments, please email osd.dfars@mail.mil. Include DFARS Case 2024–D007 in the subject line of the message.

List of Subjects in 48 CFR Parts 209, 212, 237, and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System proposes to amend 48 CFR parts 209, 212, 237, and 252 as follows:

■ 1. The authority citation for parts 209, 212, 237, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 209—CONTRACTOR QUALIFICATIONS

■ 2. Add section 209.503–70 to read as follows:

209.503–70 Waiver.

Notwithstanding FAR 9.503, for consulting services, as defined at 209.57X(b), the waiver approval authority is the Secretary of Defense and the following officials, without power of delegation below an official appointed by the President and confirmed by the Senate:

(a) The Under Secretary of Defense (Acquisition and Sustainment).

(b) The assistant secretaries of the military departments. (See PGI 209.503–70.)

■ 3. Add section 209.57X to read as follows:

209.57 X Conflicts of interest in certain consulting services.

(a) *Scope.* (1) This section implements section 812 of the National Defense Authorization Act for Fiscal Year 2024 (Pub. L. 118–31).

(2) To the extent that this section is inconsistent with FAR subpart 9.5, this section takes precedence.

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

Consulting services means advisory and assistance services, except that the term does not include the provision of products or services related to—

- (i) Compliance with legal, audit, accounting, tax, reporting, or other requirements of the laws and standards of countries; or
- (ii) Participation in a judicial, legal, or equitable dispute resolution proceeding.

Contract oversight entity means any of the following:

- (i) The contracting officer.
- (ii) The contracting officer's representative.
- (iii) The Defense Contract Management Agency.
- (iv) The Defense Contract Audit Agency.
- (v) The DoD Office of Inspector General or any subcomponent of that office.
- (vi) The Government Accountability Office.

Covered contract means a DoD contract involving consulting services.

Covered foreign entity means any of the following:

- (i) The government of the People's Republic of China, the Chinese Communist Party, the People's Liberation Army, the Ministry of State Security, or other security service or intelligence agency of the People's Republic of China.
- (ii) The government of the Russian Federation or any entity sanctioned by the Secretary of the Treasury under Executive Order 13662, Blocking Property of Additional Persons Contributing to the Situation in Ukraine.
- (iii) The government of any country if the Secretary of State determines that such government has repeatedly provided support for acts of international terrorism pursuant to any of the following:

(A) Section 1754(c)(1)(A) of the Export Control Reform Act of 2018 (50 U.S.C. 4318(c)(1)(A)).

(B) Section 620A of the Foreign Assistance Act of 1961 (22 U.S.C. 2371).

(C) Section 40 of the Arms Export Control Act (22 U.S.C. 2780).

(D) Any other provision of law.

(iv) Any entity included on any of the following lists maintained by the Department of Commerce (see the Export Administration Regulations at 15 CFR subchapter C):

(A) The Entity List in supplement no. 4 to 15 CFR part 744.

(B) The Denied Persons List as described in 15 CFR 764.3(a)(2).

(C) The Unverified List in supplement no. 6 to 15 CFR part 744.

(D) The Military End User List in supplement no. 7 to 15 CFR part 744.

(v) Any entity identified by the Secretary of Defense pursuant to section 1237(b) of the National Defense Authorization Act for Fiscal Year 1999 (Pub. L. 105–261; 50 U.S.C. 1701 note).

(vi) Any entity on the Non-Specially Designated Nationals Chinese Military-Industrial Complex Companies List maintained by the Office of Foreign Assets Control of the Department of the Treasury under Executive Order 14032, Addressing the Threat From Securities Investments That Finance Certain Companies of the People's Republic of China.

(c) *Prohibition.* The contracting officer shall not award a contract assigned a North American Industry Classification System (NAICS) code beginning with 5416 that involves consulting services to an offeror that—

- (1) Cannot certify that neither the offeror nor its subsidiaries or affiliates hold a contract involving consulting services with one or more covered foreign entities; and
- (2) Does not have a conflict-of-interest mitigation plan that is auditable by a contract oversight entity and approved by the contracting officer.

(d) *Waiver.* (1) If the prospective contractor(s) certified, in response to paragraph (c) of the provision at 252.209–70XX, Prohibition Relating to Conflicts of Interest in Consulting Services—Certification, that it or its subsidiaries or affiliates hold a contract for consulting services with one or more covered foreign entities and the offeror has not submitted an acceptable conflict-of-interest mitigation plan, the contracting officer shall—

- (i) Notify the offeror of the potential withholding of award due to the unmitigated conflict of interest; and
 - (ii) Specify that the offeror has 10 days to respond to the notification.
- (2) If the contracting officer determines that it is in the best interests of the United States to award the contract, notwithstanding the conflict of interest, the contracting officer shall request a waiver in accordance with 209.503–70.

(3) The prohibition may be waived on a case-by-case basis if an official listed at 209.503–70 determines that a waiver is necessary for national security purposes.

(4) The contracting officer shall include the waiver request and the waiver in the contract file.

(5) Not later than 30 days after approval of the waiver, the agency shall provide written notification to the House and Senate Armed Services Committees of the use of such waiver authority. The notification shall include—

(i) The specific justification for providing the waiver;

(ii) The number of offerors that did not require a waiver;

(iii) The number of offerors that were granted a waiver;

(iv) Identification of the covered foreign entity that is the subject of the waiver; and

(v) The total dollar value of the covered contract.

(e) *Solicitation provision.* Use the provision at 252.209–70XX, Prohibition Relating to Conflicts of Interest in Consulting Services—Certification, in solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial services, assigned a NAICS code beginning with 5416. Do not include the provision in solicitations for the acquisition of commercial products.

PART 212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 4. Amend section 212.301 by revising paragraph (f)(iv) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

(f) * * *

(iv) *Part 209—Contractor*

Qualifications. (A) Use the provision at 252.209–7011, Representation for Restriction on the Use of Certain Institutions of Higher Education, as prescribed at 209.170–4, to comply with section 1062 of the National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283).

(B) Use the provision at 252.209–70XX, Prohibition Relating to Conflicts of Interest in Consulting Services—Certification, as prescribed in 209.57X(e), to comply with section 812 of the National Defense Authorization Act for Fiscal Year 2024 (Pub. L. 118–31).

* * * * *

PART 237—SERVICE CONTRACTING

■ 5. Add section 237.27X to read as follows:

237.27X Consulting services.

See 209.57X for requirements related to conflicts of interest in consulting services.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 6. Add section 252.209–70XX to read as follows:

252.209–70XX Prohibition Relating to Conflicts of Interest in Consulting Services—Certification.

As prescribed in 209.57X(e), use the following provision:

Prohibition Relating to Conflicts of Interest in Consulting Services—Certification (DATE)

(a) *Definitions.* As used in this provision—

Consulting services means advisory and assistance services, except that the term does not include the provision of products or services related to—

(1) Compliance with legal, audit, accounting, tax, reporting, or other requirements of the laws and standards of countries; or

(2) Participation in a judicial, legal, or equitable dispute resolution proceeding.

Contract oversight entity means any of the following:

(1) The Contracting Officer.

(2) The Contracting Officer's Representative.

(3) The Defense Contract Management Agency.

(4) The Defense Contract Audit Agency.

(5) The DoD Office of Inspector General or any subcomponent of that office.

(6) The Government Accountability Office.

Covered contract means a DoD contract involving consulting services.

Covered foreign entity means any of the following:

(1) The government of the People's Republic of China, the Chinese Communist Party, the People's Liberation Army, the Ministry of State Security, or other security service or intelligence agency of the People's Republic of China.

(2) The government of the Russian Federation or any entity sanctioned by the Secretary of the Treasury under Executive Order 13662, Blocking Property of Additional Persons Contributing to the Situation in Ukraine.

(3) The government of any country, if the Secretary of State determines that such government has repeatedly provided support

for acts of international terrorism, pursuant to any of the following:

(i) Section 1754(c)(1)(A) of the Export Control Reform Act of 2018 (50 U.S.C. 4318(c)(1)(A)).

(ii) Section 620A of the Foreign Assistance Act of 1961 (22 U.S.C. 2371).

(iii) Section 40 of the Arms Export Control Act (22 U.S.C. 2780).

(iv) Any other provision of law.

(4) Any entity included on any of the following lists maintained by the Department of Commerce (see the Export Administration Regulations at 15 CFR subchapter C):

(i) The Entity List in supplement no. 4 to 15 CFR part 744.

(ii) The Denied Persons List as described in 15 CFR 764.3(a)(2).

(iii) The Unverified List in supplement no. 6 to 15 CFR part 744.

(iv) The Military End User List in supplement no. 7 to 15 CFR part 744.

(5) Any entity identified by the Secretary of Defense pursuant to section 1237(b) of the National Defense Authorization Act for Fiscal Year 1999 (Pub. L. 105–261; 50 U.S.C. 1701 note).

(6) Any entity on the Non-Specially Designated Nationals Chinese Military-Industrial Complex Companies List maintained by the Office of Foreign Assets Control of the Department of the Treasury under Executive Order 14032, Addressing the Threat from Securities Investments that Finance Certain Companies of the People's Republic of China.

(b) *Prohibition.* If the Offeror cannot certify that neither the Offeror nor any of its subsidiaries or affiliates hold a contract that involves consulting services with one or more covered foreign entities, DoD cannot award to the Offeror a contract assigned a North American Industry Classification System code beginning with 5416.

(c) *Certification.* The Offeror certifies that—

(1)(i) It does ☐ does not ☐ hold a contract for consulting services with one or more covered foreign entities; and

(ii) Its subsidiaries or affiliates do ☐ do not ☐ hold a contract for consulting services with one or more covered foreign entities; and

(2) It does ☐ does not ☐ maintain a conflict-of-interest mitigation plan described in paragraph (d) of this provision.

(d) *Conflict-of-interest mitigation plan.* If the Offeror answered in the affirmative in paragraphs (c)(1) and (2) of this provision, the Offeror may contact the Contracting Officer for guidance on submitting the Offeror's conflict-of-interest mitigation plan.

(1) The Offeror's conflict-of-interest mitigation plan shall be auditable by a contract oversight entity and shall include—

(i) An identification, unless otherwise prohibited by law or regulation, of any covered contracts of the Offeror or its subsidiaries or affiliates with a covered foreign entity. If the Offeror is unable to identify one or more covered foreign entities due to confidentiality obligations, the Offeror shall identify such entities as a covered foreign entity;

(ii) A written analysis, including a course of action for avoiding, neutralizing, or mitigating the actual or potential conflict of interest of such a covered contract;

(iii) A description of the procedures by which the Offeror or its subsidiaries or affiliates will ensure that individuals who will perform the scope of a covered contract will not, for the duration of such contract, also provide any consulting services to any covered foreign entity; and

(iv) A description of the procedures by which the Offeror or its subsidiaries or affiliates will submit to the contract oversight entities a notice of an unmitigated conflict of interest with respect to a covered contract within 15 days of determining that such a conflict has arisen.

(2) If the Contracting Officer approves the Offeror's conflict-of-interest mitigation plan, the Contracting Officer will incorporate the plan into any contract awarded to the Offeror resulting from this solicitation.

(End of provision)

[FR Doc. 2024–21099 Filed 9–25–24; 8:45 am]

BILLING CODE 6001–FR–P



FEDERAL REGISTER

Vol. 89

Thursday,

No. 187

September 26, 2024

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 438, and 447

Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 433, 438, and 447**

[CMS-2434-F]

RIN 0938-AU28

Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule implements policies in the Medicaid Drug Rebate Program (MDRP) related to the new legislative requirements in the Medicaid Services Investment and Accountability Act of 2019 (MSIAA), which address drug misclassification, as well as drug pricing and product data misreporting by manufacturers. Additionally, we are finalizing several other proposed program integrity and program administration provisions or modifications in this final rule, including revising and finalizing key definitions used in the MDRP. This rule also finalizes a provision not directly related to MDRP that makes revisions to the third-party liability regulation due to amendments made by the Bipartisan Budget Act (BBA) of 2018. We also are finalizing our proposal to rescind revisions made by the December 31, 2020 final rule “Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements” (“the 2020 final rule”) to the Determination of Best Price and Determination of Average Manufacturer Price (AMP) sections.

DATES: These regulations are effective on November 19, 2024.

Applicability Dates: In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table 1), which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Omar Alemi, 720-853-2724, omar.alemi@cms.hhs.gov, for issues

related to the definition of covered outpatient drug (COD) and removal of manufacturer rebate cap.

Ruth Blatt, 410-786-1767, ruth.blatt@cms.hhs.gov, for issues related to the definitions of noninnovator multiple-source drug, market date, and COD.

Ginger Boscas, 410-786-3098, ginger.boscas@cms.hhs.gov, for issues related to third-party liability.

Michael Forman, 410-786-2666, michael.forman@cms.hhs.gov, for issues related to physician-administered drugs.

Charlotte Hammond, 410-786-1092, charlotte.hammond@cms.hhs.gov, for issues related to diagnosis on prescriptions and professional dispensing fees.

Mickey Morgan, 443-745-3950, mickey.morgan1@cms.hhs.gov, for issues related to drug cost transparency in Medicaid managed care contracts and accounting for accumulated price concessions from ‘stacking’ when determining best price.

Lisa Shochet, 410-786-5445, lisa.shochet@cms.hhs.gov, for issues related to Bank Identification Number and Processor Control Number (BIN/PCN).

Terry Simananda, 410-786-8144, terry.simananda@cms.hhs.gov, for issues related to internal investigation, Collection of Information, and Regulatory Impact Analysis sections.

Whitney Swears, 410-786-6543, whitney.swears@cms.hhs.gov, for issues related to time limitation on audits and the definition of manufacturer.

Cathy Traugott, 720-853-2785, catherine.traugott@cms.hhs.gov, for issues related to drug misclassifications, definition of vaccine, and a drug price verification process through data collection survey.

SUPPLEMENTARY INFORMATION:**I. Background****A. Introduction**

Under the Medicaid program, section 1902(a)(54) of the Social Security Act (the Act) provides States with the option of providing coverage of prescribed drugs as described in section 1905(a)(12) of the Act, and to date, all States have elected to do so. Section 1903(a) of the Act provides for Federal Financial Participation (FFP) in State expenditures for these covered outpatient drugs (CODs). Coverage of CODs under the option provided by section 1902(a)(54) of the Act must comply with the requirements of section 1927 of the Act. Section 1927 of the Act governs the Medicaid Drug Rebate Program (MDRP) and payment for CODs, which are defined in section 1927(k)(2) of the Act. In general, for

payment to be made available for CODs under section 1903(a) of the Act, manufacturers must enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act. See also section 1903(i)(10) of the Act conditioning FFP in medical assistance for drugs covered under section 1902(a)(54) on the manufacturer of the drug having an NDRA. The rebates paid by manufacturers to States help to partially offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries.

The amount of the rebate is determined by a formula set forth in section 1927(c) of the Act. Generally, the formula to calculate the rebate that applies to a particular drug depends on whether the drug is classified as (1) a single source drug (S drug) or innovator multiple source drug (I drug), commonly referred to as a brand-name drug, or (2) other drugs, which include noninnovator multiple source drugs (N drug), commonly referred to as generic drugs, among others. Generally, pursuant to section 1927 of the Act, drugs classified as single source drugs or innovator multiple source drugs pay higher rebates than those that are classified as an “other drug,” such as noninnovator multiple source drugs.

Consistent with section 1927(b)(3)(A) of the Act, a manufacturer must report and certify certain drug product and drug pricing information for CODs to CMS not later than 30 days after the last day of each month and certain drug product and drug pricing information 30 days after the last day of each quarter of a rebate period. If a manufacturer fails to submit timely information, or misreports information, we may be unable to establish accurate Unit Rebate Amounts (URAs) due to the misreporting or late reporting. While we provide URAs to the States each quarter to help facilitate billing manufacturers for rebates, it is ultimately the manufacturer’s responsibility to ensure accurate rebates are paid to States for their CODs.

Prior to the enactment of the Medicaid Services Investment and Accountability Act of 2019 (MSIAA) (Pub. L. 116-16; enacted April 18, 2019), section 1927(k)(7)(A)(iv) of the Act defined a single source drug as a covered outpatient drug which is produced or distributed under an original new drug application (NDA). Section 1927(k)(7)(A)(ii) of the Act similarly defined an innovator multiple source drug as a multiple source drug that was originally marketed under an original NDA. A noninnovator multiple source drug was defined at section

1927(k)(7)(A)(iii) of the Act as a multiple source drug that is not an innovator multiple source drug. MSIAA made several revisions to these definitions, including adding a provision to ratify CMS' existing policy to permit certain exceptions from the definitions if a narrow exception applies, as described in § 447.502 or any successor regulation.

This narrow exception process in § 447.502 was created in the 2016 final rule entitled "Medicaid Program; Covered Outpatient Drugs"¹ (2016 COD final rule), under which drug manufacturers could submit a request for a narrow exception to allow individual drugs approved under an NDA to be treated as if they were approved under an abbreviated new drug application (ANDa) and classified as noninnovator multiple source drugs prospectively from the effective date of the 2016 COD final rule. Instructions to manufacturers regarding this process were included in Manufacturer Release #98, May 2, 2016.² The 2016 COD final rule did not, however, excuse manufacturers from their obligation to correctly report drugs approved under an NDA, as either single source or innovator multiple source drugs prior to the effective date of the 2016 COD final rule, which was April 1, 2016. This narrow exception process was codified into statute in MSIAA when the Congress removed the word "original" from the definitions of single source drug and innovator multiple source drug, thereby confirming CMS' pre 2016 interpretation.

We published the proposed rule (88 FR 34238–34296) on May 26, 2023, and provided a 60-day comment period. A total of 128 comments were received. We are now publishing the final rule. We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from other parts of this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a

provision is necessarily dependent on another, the context generally makes that clear.

B. Amendments Made by the Medicaid Services Investment and Accountability Act of 2019 (MSIAA) to Section 1927 of the Act Regarding MDRP Drug Classification Enforcement and Penalties

Section 6 of MSIAA, titled "Preventing the Misclassification of Drugs Under the Medicaid Drug Rebate Program," amended sections 1903 and 1927 of the Act to (1) specify the definitions for single source drug, innovator multiple source drug, and noninnovator multiple source drug, and (2) to provide the Secretary with additional compliance, oversight and enforcement authorities to ensure compliance with program requirements with respect to manufacturers' reporting of drug product and pricing information, which includes the appropriate classification of a drug. Drug classification refers to how a drug should be classified—as a single source drug, innovator multiple source drug, or noninnovator multiple source drug—for the purposes of determining the correct rebates that each manufacturer owes the States.

Although much of this law is self-implementing, we proposed a series of regulatory amendments at §§ 447.509 and 447.510 to implement and codify the statutory changes in regulation. We proposed that misclassification of a drug under the MDRP has occurred or is occurring when a manufacturer reports and certifies to the agency a drug category or drug product information relating to that COD that is not supported by the statutory and regulatory definitions of S, I, or N drug. We also defined a misclassification as a situation in which a manufacturer is correctly reporting its drug category or drug product information for a COD but is paying a different rebate amount to the States than is supported by the classification.

MSIAA also amended the Act to expressly require a manufacturer to report not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require for each of the manufacturer's covered outpatient drugs. We proposed a definition of "drug product information" for the purposes of the MDRP.

Similarly, MSIAA amended the Act to specify that the reporting of false information, including information related to drug pricing, drug product information, and data related to drug

pricing or drug product information, would also be subject to possible civil monetary penalties (CMPs) by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG), and to provide specific new authority to the Secretary to issue CMPs related to knowing misclassifications of drug product or misreported information. These OIG authorities are not the subject of this rulemaking.

Under MSIAA, if a manufacturer fails to correct the misclassification of a drug in a timely manner after receiving notification from the agency that the drug is misclassified, in addition to the manufacturer having to pay past unpaid rebates to the States for the misclassified drug if applicable, the Secretary can take any or all of the following actions, including correcting the misclassification, suspending the misclassified drug from the MDRP, imposing CMPs, or ultimately terminating the manufacturer's participation in the MDRP.

Codifying these statutory amendments in our regulations provides an opportunity for the agency to give additional clarity to and guidance on the new legal authorities for ensuring oversight of, compliance with, and enforcement of the provisions of the MDRP, and ultimately to ensure that Federal and State programs are receiving appropriate rebates and that CMS continues to be a stringent steward of taxpayer monies.

C. MDRP Program Administration Proposed Changes

In order to increase efficiency and economy of directing overall MDRP operations, resources, and activities to better facilitate the needs of Medicaid beneficiaries, we proposed a number of new regulatory policies and clarifications of existing policies. Specifically, consistent with our statutory authorities, we proposed to define, specify, or amend the definitions for COD, internal investigation (for restatement purposes outside of a 3-year time window), manufacturer (for National Drug Rebate Agreement (NDRA) purposes), market date, noninnovator multiple source drug, drug product information, and vaccine for the purposes of the MDRP. We also proposed to specify that the rebate provisions for a drug other than a single source drug or an innovator multiple source drug apply to an array of drugs, including those that may not satisfy the definition of noninnovator multiple source drug.

In addition, we proposed new policies, including to add a time

¹ <https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf>.

² <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-098.pdf>.

limitation on manufacturers' ability to initiate audits with States, to further clarify and establish the requirements for FFS pharmacy reimbursement, and to clarify the required collection of all National Drug Codes (NDCs) for single and multiple source physician-administered drugs to receive FFP and secure manufacturer rebates.

We also proposed to revise Medicaid managed care standard contract requirements to adopt a requirement for the inclusion of Bank Identification Number and Processor Control Number (BIN/PCN) numbers on Medicaid enrollee identification cards for pharmacy benefits, as well as enhance drug cost transparency by adopting specific requirements relating to the third-party administration of the pharmacy benefit. We provide additional background later in this rule.

1. Proposal To Modify the Definition of Covered Outpatient Drug

In the 2016 COD final rule (81 FR 5278), we finalized a regulatory definition of covered outpatient drug in § 447.502 that substantially mirrors the statutory definition and is consistent with section 1927(k)(3) of the Act. The definition includes a limiting definition which exempts from the COD definition, and thus from rebates, any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug) certain health care setting or situations described in section 1927(k)(3). However, we never clarified what the term "direct reimbursement" means for the purposes of defining those situations under which a State could bill a manufacturer for a rebate for a COD when the COD is part of an inclusive payment for the COD and related services. In regulation, we proposed to define the term direct reimbursement at § 447.502 so that States know those situations in which the limiting definition would not apply such that a State could bill for a rebate. CMS received several thoughtful comments on this issue, and based on these comments, we realized the proposed language did not adequately clarify the policy. Thus, we are further refining the definition to more clearly delineate the situations in which the limiting definition would not apply.

2. Proposed Definition of an Internal Investigation for Purposes of Pricing Metric Revisions

In accordance with section 1927(b)(3) of the Act, § 447.510 of the applicable

regulations, and the terms of the NDRA, manufacturers are required to report certain pricing and drug product information to CMS on a timely basis or else they could incur penalties or other compliance and enforcement measures. In the 2016 COD final rule, we established § 447.510(b)(1), which provides that a manufacturer must report to CMS any revision to AMP, best price, customary prompt pay discounts, or nominal prices (pricing data) for a period not to exceed 12 quarters from the quarter in which the data were due unless enumerated exceptions apply. See § 447.510(b)(1)(i) through (vi).

The existing regulation at § 447.510(b)(1)(v) provides an exception to the 12-quarter price reporting rule if the change is being made to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation or an OIG or Department of Justice (DOJ) investigation. However, up to this point, we have not defined the term internal investigation, which has led to different interpretations of the nature of an internal investigation. Therefore, we proposed to add a definition of internal investigation at § 447.502 and additional clarity around the 12-quarter price reporting rule at § 447.510. Based on comments we received, we are finalizing as proposed except we are adding the term "possible" to "fraud, abuse or violation of law or regulation".

3. Proposal To Modify the Definition of Manufacturer for National Drug Rebate Agreement (NDRA) Compliance Purposes

We proposed to further refine the definition of manufacturer to clarify that a manufacturer includes all other manufacturers that are associated or affiliated with that manufacturer. This was intended to clarify that once a manufacturer has entered into a rebate agreement with CMS, all entities (with their applicable labeler codes) that are associated or affiliated with a manufacturer must have a rebate agreement in effect in order for the manufacturer to satisfy the statutory requirement that the manufacturer have a rebate agreement in effect with the Secretary.

We appreciate the thoughtful comments received on this issue, and we determined not to finalize the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

4. Proposal To Establish a Definition of Market Date for a COD for the Purposes of Determining a Base Date AMP for a COD

The rebates due by manufacturers are calculated based on statutory formulas described in section 1927(c) of the Act and consist of a basic rebate and, in some cases, an additional rebate that is applicable when an increase in the AMP, with respect to each dosage, form, and strength of a drug, exceeds the rate of inflation. A key factor in the calculation of the additional rebate is the base date AMP³ of the drug, a value that is determined based on the market date of the drug. Manufacturers are required to report the market date of each dosage form and strength of a COD for all of their CODs. The term market date has not been previously defined in regulation for purposes of the MDRP, and CMS has received numerous questions regarding the determination of market date. Accordingly, we proposed to define the term market date at § 447.502 for the purpose of the MDRP and are finalizing as proposed.

5. Proposal To Modify the Definition of Noninnovator Multiple Source Drug

As discussed previously in the proposed rule, section 6(c) of MSIAA included a number of amendments to statutory definitions in section 1927 of the Act. One of the amendments to the statutory definitions was to remove the phrase "was originally marketed" from the definition of an I drug and replace it with "is marketed." We also made conforming changes to the regulatory definition of an I drug in the 2020 final rule.

These amendments should have prompted a corresponding change to the regulatory definition of noninnovator multiple source (N) drug in the 2020 final rule to align with the statutory and regulatory change to the definition of an I drug, however we neglected to include the change. Therefore, we proposed to amend the definition of an N drug at § 447.502 to maintain the clear distinction between an I drug and an N drug and are finalizing as proposed.

6. Proposal To Define Vaccine for the Purposes of the MDRP Only

Section 1927(k)(2)(B) of the Act specifically excludes vaccines from the definition of COD for purposes of the MDRP. This exclusion is codified in paragraph (1)(iv) of the regulatory definition of COD at § 447.502. Section 1927 of the Act does not define vaccine.

³ The terms "base date AMP," "baseline AMP," and "base AMP" are used interchangeably within this document.

We proposed a definition of vaccine at § 447.502 for the purpose of identifying products that do not satisfy the definition of COD and are therefore not subject to possible required coverage under the prescribed drugs benefit consistent with section 1927 of the Act and applicable rebate liability under the MDRP. We noted that the regulatory definition of vaccine is intended to be established solely for the purposes of the MDRP and is intended to be applicable only to that program and Medicaid expansion CHIP programs (that is, CHIP programs operating pursuant to 42 CFR 457.70(a)(2) and (c)). It is not intended to apply under any title XIX statutory provisions other than section 1927(k)(2), or to separate CHIPs operating pursuant to 42 CFR 457.70(a)(1) and (d), or for purposes of the Vaccines for Children (VFC) Program. Nor is it intended to apply to any other programs within CMS or any other agencies within HHS (for example, the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), or Health Resources and Services Administration (HRSA)). Rather, we stated that the proposed changes would only specify which products are vaccines and are therefore excluded from the definition of a COD under the MDRP and thus are not subject to section 1927, including to MDRP rebate liability; the proposed changes would not apply to any applicable Federal or State requirements to cover vaccines for Medicaid beneficiaries, as applicable. We appreciate the thoughtful comments we received on this issue. At this time, we are not finalizing the proposed regulatory definition. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

7. Proposal To Account for Stacking When Determining Best Price

We proposed to revise § 447.505(d)(3) to add language to make clearer that the manufacturer must adjust the best price for a drug for a rebate period if cumulative discounts, rebates, or other arrangements to best price eligible entities subsequently adjust the prices available from the manufacturer, and that those discounts, rebates, or other arrangements must be “stacked” for a single transaction to determine a final price realized by the manufacturer for a drug. CMS received a number of thoughtful comments on this issue, and we have determined not to finalize the proposed regulation changes at this time. We are continuing to review the input provided by commenters. We intend to collect information through a

separate Paperwork Reduction Act (PRA) request to collect additional information related to manufacturers’ stacking methodologies, which may inform future rulemaking on this topic.

8. Proposal To Establish a Time Limitation for Audits Over Utilization Data With States: 12-Quarter Rebate Dispute Time Limitation

Currently, there is no time limit for a manufacturer to initiate an audit or resolve previously disputed State utilization data with respect to rebates owed, and section 1927 of the Act does not impose a specific timeframe on a manufacturer’s audit authority. We proposed to limit the time period during which manufacturers may initiate disputes, hearing requests, and audits of State-invoiced utilization units to 12 quarters from the last day of the quarter from the date of State invoice to the manufacturer. Upon reviewing comments, we believe referencing the invoice postmark date instead of the date of the State invoice offers the same clarity for both States and Manufacturers on the timeline initiation and would align with previous DP policy. Therefore, we are finalizing as proposed, with the exception of referencing “postmark date” instead of “the date of the State invoice”.

9. Proposal Regarding Drug Price Verification Through Data Collection

Section 1927(b)(3)(B) of the Act authorizes the Secretary to “survey wholesalers and manufacturers that directly distribute their [CODs], when necessary, to verify manufacturer prices” reported under section 1927(b)(3)(A) of the Act. Under this authority, we proposed rules to describe those situations when it would be considered “necessary” for such surveys to be sent to manufacturers and wholesalers, and the information that would be requested to use in order to verify the reported prices at issue.

We appreciate the thoughtful comments we received on this issue, and we determined not to finalize the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

10. Proposal To Clarify and Establish Requirements for FFS Pharmacy Reimbursement

In the 2016 COD final rule, we finalized at § 447.518 moving FFS pharmacy reimbursement to an actual acquisition cost-based reimbursement, under which pharmacists would be paid for the ingredient costs of the drug that was dispensed, and a professional

dispensing fee (PDF) that reflected their costs of dispensing. We proposed to revise § 447.518, “State plan requirements, findings, and assurances,” in paragraph (d)(1) to clarify State requirements regarding pharmacy ingredient costs and professional dispensing fees to be consistent with the applicable statutory and regulatory requirements, specifying in particular that any dispensing fee surveys must be based on actual pharmacy dispensing costs data and not market research data. We are finalizing as proposed.

11. Proposals Relating to Section 1927(a)(7) of the Act and Federal Financial Participation (FFP): Conditions Relating to Physician-Administered Drugs (PADs)

In accordance with section 1927(a)(7) of the Act, for payment to be available under section 1903 of the Act, and for States to secure applicable Medicaid rebates, States are to provide for the collection and submission of utilization data and coding (such as J-codes⁴ and NDC numbers) for a COD that is a physician-administered single source drug as determined by the Secretary, or that is a multiple source drug that is determined by the Secretary to be a top 20 high dollar volume PAD dispensed under Medicaid (as identified on a published list).⁵ Regulations at § 447.520 were established to implement these statutory provisions in the final rule entitled “Medicaid Program; Prescription Drugs” (72 FR 39142, 39162) (hereinafter referred to as the 2007 final rule), specifying the conditions for FFP for PADs.⁶

We proposed to amend § 447.520 to require States to collect NDC information on all covered outpatient single and multiple source PADs and to specify that States must invoice for rebates for all covered outpatient PADs to receive FFP and secure manufacturer rebates. We are finalizing as proposed but have added a discussion of our statutory authority for extending this requirement by regulation beyond the top 20 multiple source drugs already required by statute.

⁴ J codes are a subset of the Healthcare Common Procedure Coding System (HCPCS) Level II code set used to primarily identify injectable drugs.

⁵ <https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/physician-administered-drugs-pad/index.html>.

⁶ <https://www.govinfo.gov/content/pkg/CFR-2007-title42-vol4/pdf/CFR-2007-title42-vol4-sec447-520.pdf>.

12. Proposal Related to Suspension of a Manufacturer's Drug Rebate Agreement

We proposed regulatory changes to further implement section 1927(b)(3)(C)(i) of the Act, which provides authority to suspend a rebate agreement for a manufacturer's failure to timely report drug pricing or drug product information to the agency, when there is a continued failure to report after a 90-calendar day deadline is imposed by the agency. Specifically, we proposed in § 447.510(i) that a manufacturer must report information required under § 447.510(a) and (d), and the failure to report such information to the agency after the end of an imposed 90-calendar day period would result in suspension of the manufacturer's rebate agreement, and that such agreement would not be reinstated until such information was reported in full and certified, but not for a period of suspension of less than 30 calendar days. We are finalizing as proposed.

13. Proposals Related to Managed Care Plan Standard Contract Requirements

a. Requirement of BIN/PCN Inclusion on Medicaid Managed Care Pharmacy Identification Cards

Patients enrolled in health care plans, including in Medicaid managed care plans such as Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), or prepaid ambulatory health plans (PAHPs), generally use enrollee identification cards at the pharmacy so they can obtain prescription drug benefits, as well as allow pharmacies to process and bill claims in real-time. Health plans use two codes on the card to identify a patient's prescription health insurance and benefits—the National Council for Prescription Drug Programs (NCPDP) Processing Bank Identification Number (BIN) and Processor Control Number (PCN). This information, along with a group number identifier, can specify that a patient is covered by a specific insurance group, such as being a Medicaid managed care enrollee.

Without the BIN, PCN, and group number identifiers, it is often difficult to determine from a Medicaid managed care enrollee's identification card if he or she is covered under a Medicaid managed care plan or under non-Medicaid coverage, such as an employer-sponsored group health plan or individual market insurance, offered by the same organization or entity that offers the Medicaid managed care plan.

While the use of Medicaid-specific BIN, PCN, and group number identifiers does not assist in identifying claims for drugs purchased under the 340B Drug

Pricing Program (340B Program), it may help States and their managed care plans avoid invoicing for rebates on 340B drugs by identifying which plans are covered under Medicaid. Section 340B(a)(5)(A) of the Public Health Service Act (the PHS Act) prohibits duplicate discounts for drugs purchased under the MDRP. Identifying claims where the dispensed drug has been discounted under the 340B Program is necessary to avoid duplicating that discount in the MDRP.

Therefore, under the authority of section 1902(a)(4) of the Act, to ensure effective implementation of and compliance with sections 1927(a)(5)(C) and 1927(j)(1) of the Act, we proposed to amend § 438.3(s) to require States to require (via standard contract requirements) MCOs, PIHPs, and PAHPs that provide coverage of CODs to assign and exclusively use unique Medicaid BIN, PCN, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits. Based on comments received, we are changing the requirement to be a unique BIN/PCN combination with a group number identifier, as well as the effective date.

b. Drug Cost Transparency in Medicaid Managed Care Contracts

Medicaid managed care plans often contract with a subcontractor Pharmacy Benefit Manager (PBM) to operate the pharmacy benefit provided to Medicaid beneficiaries. For a Medicaid managed care plan to appropriately calculate and report its Medical Loss Ratio (MLR) under § 438.8, the plan must know from the subcontractor certain information relating to how much of the payments made to the Medicaid managed care plan by the State were used to pay for health care services and other specific categories outlined in § 438.8. To correctly report the MLR, a Medicaid managed care plan must distinguish between expenses that are for covered benefits (such as incurred claims for health care services and drug costs) and administrative expenses, such as fees paid to its PBM for PBM services (for example, claims adjudication and processing prior authorization requests).

Therefore, we proposed that MCOs, PIHPs, and PAHPs that provide coverage of CODs require any subcontractor to report the amounts related to the incurred claims described in § 438.8(e)(2) separately from any administrative costs, fees, and expenses of the subcontractor. Based on comments received, we are finalizing as proposed, with a few clarifying changes. We are adding "MCO, PIHP or PAHP" in a few places to be consistent with

other paragraphs in 42 CFR 438.3(s) and are adding a subsection to include an effective date, which will be the first rating period for contracts beginning on or after 1 year following the effective date of the rule.

14. Proposal To Rescind Revisions Made by the December 31, 2020 Final Rule To Determination of Best Price (§ 447.505) and Determination of Average Manufacturer Price (AMP) (§ 447.504) Consistent With Court Order

On May 17, 2022, the United States District Court for the District of Columbia vacated and set aside the "accumulator adjustment rule of 2020" in response to a complaint filed against the Secretary regarding the accumulator provisions within the 2020 final rule "Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements." This final rule had revised the conditions for excluding patient assistance from AMP at § 447.504(c)(25) through (29) and (e)(13) through (17), and best price at § 447.505(c)(8) through (12), to add language (effective January 1, 2023) that would require manufacturers to "ensure" the full value of the assistance provided by patient assistance programs is passed on to the consumer and that the pharmacy, agent, or other AMP or best price eligible entity does not receive any price concession. While the district court's order focused on the changes to the patient assistance program exclusions from best price determinations, for consistency, we proposed to withdraw the changes related to patient assistance to both the AMP and best price sections made by the 2020 final rule so that the regulations would revert back to the language that has been in place since 2016. We are finalizing this provision as proposed.

15. Proposals Related to Amendments Made by the American Rescue Plan Act of 2021—Removal of the Manufacturer Rebate Cap (100 Percent AMP)

Section 9816 of the American Rescue Plan Act of 2021 (Pub. L. 117–2, enacted March 11, 2021) sunsets the limit on maximum rebate amounts for single source and innovator multiple source drugs by amending section 1927(c)(2)(D) of the Act to add "and before January 1, 2024," after "December 31, 2009." In accordance with section 1927(c)(3)(C)(i) of the Act and the special rules for application of the provision in section

1927(c)(3)(C)(ii)(IV) and (V) of the Act, this sunset provision also applies to the limit on maximum rebate amounts for CODs other than single source or innovator multiple source drugs. Therefore, to conform § 447.509 with section 1927(c)(2)(D) of the Act, as amended by the American Rescue Plan Act of 2021, and sections 1927(c)(3)(C)(i), (ii)(IV), and (ii)(V) of the Act, we proposed to make conforming changes to § 447.509 to reflect the removal of the limit on maximum rebate amounts for rebate periods beginning on or after January 1, 2024. We are finalizing this provision as proposed.

16. Request for Information—Comments on Issues Relating To Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment

We solicited comments on the patient care, clinical, and operational impact of requiring that a patient's diagnosis be included on a prescription as a condition of a State receiving FFP for that prescription. We were particularly interested in understanding any operational implications, privacy related concerns, associated burden, and approaches to negate any foreseeable impact on beneficiaries and providers, including what steps would be needed by States to successfully implement a

Medicaid requirement for diagnosis on prescriptions.

We appreciate the thoughtful comments we received on this issue, and we determined we are not moving forward with any proposed regulations regarding this topic at this time.

17. Background on Coordination of Benefits/Third Party Liability Regulation Due to Bipartisan Budget Act of 2018 (BBA 2018)

Medicaid is generally the payer of last resort, which means that certain other available resources—known as third party liability, or TPL—must be used before Medicaid pays for services received by a Medicaid-eligible individual. Title XIX of the Act requires State Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid. Section 53102 of the Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018) amended the TPL provision at section 1902(a)(25) of the Act.

Specifically, section 1902(a)(25)(A) of the Act requires that States take all reasonable measures to ascertain the legal liability of third parties to pay for care and services available under the plan. That provision further specifies that a third party is any individual, entity, or program that is or may be liable to pay all or part of the expenditures for medical assistance

furnished under a State plan. Section 1902(a)(25)(A)(i) of the Act specifies that the State plan must provide for the collection of sufficient information to enable the State to pursue claims against third parties.

To update the regulation for the recent statutory changes, a final rule was published on December 31, 2020, which went into effect on March 1, 2021, to include changes as authorized under the BBA 2018. We submitted a correction due to an omission in the regulation text to require a State to make payments without regard to TPL for pediatric preventive services unless the State has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for up to 90 days.

D. Applicability and Compliance Timeframes

Generally, we are finalizing that this rule, including the proposals being finalized herein, will be effective 60 days after publication of this final rule, with the exception of two provisions in the Standard Medicaid Managed Care Contract Requirements section. We are including Table 1 with these provisions and relevant timing information and dates. We encourage all interested parties to confirm the applicability dates indicated in this final rule for any changes from the proposed.

TABLE 1—APPLICABILITY DATES

Regulation text	Applicability date
§ 438.3(s)(7)	First rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following November 19, 2024.
§ 438.3(s)(8)	First rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following November 19, 2024.

II. Summary of Proposed Provisions, Analysis of and Responses to Public Comments, and Provisions of the Final Rule

The proposed rule to implement regulatory policies in the Medicaid Drug Rebate Program (MDRP) related to the new legislative requirements in the Medicaid Services Investment and Accountability Act of 2019 (MSIAA), which address drug misclassification, as well as drug pricing and product data misreporting by manufacturers, was published on May 26, 2023 (88 FR 34238). As discussed in the proposed rule, we also made proposals to enhance program integrity and improve program administration for the MDRP. The proposals included a time limitation on manufacturers initiating audits with States, clarifications and requirements for State fee-for-service (FFS) pharmacy reimbursement, and the establishment

of conditions relating to States claiming Federal Financial Participation (FFP) for physician-administered drugs (PADs). Other proposals included two new requirements for contracts between States and their Medicaid managed care plans in connection with coverage of covered outpatient drugs (CODs). In addition, the rule included a proposal not directly related to the MDRP that would modify the third-party liability regulation based on the Bipartisan Budget Act of 2018 (BBA of 2018). Finally, the proposed rule solicited comments related to the issues, benefits, and challenges of requiring the inclusion of diagnoses on Medicaid prescriptions.

We received 128 comments from drug manufacturers, membership organizations, law firms, pharmacy benefit managers (PBMs), State Medicaid agencies, advocacy groups,

not-for-profit organizations, consulting firms, health care providers, employers, health insurers, health care associations, and individuals. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding the proposed changes.

We also received public comments on this regulation that were out of scope for this rulemaking, and, therefore, are not being addressed in this rule. The following summarizes comments about the proposed rule in general or about specific issues that are not addressed in this final rule.

Comment: Several commenters submitted comments that were outside of the scope of the proposed rule. Examples of out-of-scope comments include but are not limited to whether Medicaid accepts JW/JZ modifiers when billing radiopharmaceuticals at free-

standing radiology offices, the amount charged for a specific drug per month, and comments on CMS' "Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments," that CMS issued on February 9, 2023.

Response: We appreciate commenters' interest in these topics. However, because these comments are outside of the scope of the proposed rule, we are not addressing them in this final rule.

Comment: A commenter stated that Federal agencies must align their rules and proposals to ensure compatibility. The commenter believes there are a variety of currently proposed, pending, or expected rules from CMS and the Office of the National Coordinator for Health Information Technology (ONC) that are not completely independent from each other; they noted, in some cases, there may be components of different rules that contradict each other, and in other cases, they may be written in ways that unnecessarily increase the burden on one or more parties subject to the rule. Specifically, the commenter mentioned CMS discusses requiring NDC codes for medications in this rule, but the recent ONC Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule discusses the possibility of deprecating support for NDC codes in its certification programs in favor of always requiring use of RxNorm for medications. Concerns were raised that the rules were not coordinated so that their requirements are compatible and executable without placing additional burden on individuals or organizations that need to implement more than one rule.

Response: We appreciate the request for Federal agencies to align their rules to ensure compatibility. We are addressing only those proposals that were part of the proposed rule (88 FR 34238 through 34296). See also the discussion in section II.L., Federal Financial Participation (FFP): Conditions Relating to Physician Administered Drugs related to the HTI-1 final policy and CMS and ONC collaboration.

Comment: A commenter requested CMS postpone finalizing the proposals in the proposed rule. The commenter encouraged CMS to actively seek additional feedback from interested parties, including individuals and advocacy organizations who represent those most affected by Medicaid coverage challenges.

Response: Through the rulemaking process, the proposed rule was published, and the public was provided the opportunity to comment on the proposed rule's provisions. We have reviewed and addressed public comments and will proceed with finalizing the rule as noted herein.

A. Payment of Claims (42 CFR 433.139)

In the proposed rule, we included regulatory revisions that would make technical changes to the process for making payment of Medicaid claims. As background, we noted that in 1980, under the authority in section 1902(a)(25)(A) of the Act, we issued regulations at part 433, subpart D, that established requirements for State Medicaid agencies to support the coordination of benefits (COB) effort by identifying third party liability. We pointed out that § 433.139(b)(3)(i) and (b)(3)(ii)(B) detail the exception to standard COB cost avoidance by allowing pay and chase for certain types of care, as well as the timeframe allowed prior to Medicaid paying claims for certain types of care.

To better align our regulations with statute, we proposed to revise § 433.139(b)(3)(i) by adding—"that requires a State to make payments without regard to third party liability for pediatric preventive services unless the State has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for up to 90 days." We also proposed to revise § 433.139(b)(3)(i) and (b)(3)(ii)(B) by adding "within" prior to the waiting periods Medicaid has to pay claims for preventive pediatric and medical child support claims. Additionally, we proposed to revise § 433.139(b)(3)(ii)(B) by removing "from" and replacing it with "after;" and by removing "has not received payment from the liable third party" and adding the following language at the end of the sentence "provider of such services has initially submitted a claim to such third party for payment for such services, except that the State may make such payment within 30 days after such date if the State determines doing so is cost-effective and necessary to ensure access to care." These revisions in language would permit States to pay claims sooner than the specified waiting periods, when appropriate.

We received two public comments on this proposal. The following is a summary of the comments we received and our response.

Comment: The commenters stated that they were in support of our proposed regulation changes.

Response: We appreciate the support on this section.

After consideration of public comments on these provisions, we are finalizing as proposed.

B. Standard Medicaid Managed Care Contract Requirements (§ 438.3(s))

1. BIN/PCN on Medicaid Managed Care Enrollee Identification Cards

In the proposed rule, we included a provision to require States that contract with MCOs, PIHPs, or PAHPs that provide coverage of CODs, to require those managed care plans to assign and exclusively use unique Medicaid-specific BIN, PCN, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits. Although not required to issue enrollee identification cards, it is a standard business practice for the MCOs, PIHPs, and PAHPs to routinely issue such cards for pharmacy benefits for Medicaid enrollees. We proposed that the States' managed care contracts with MCOs, PIHPs, and PAHPs must comply with this new requirement no later than the beginning of the State's next rating period for Medicaid managed care contracts following the effective date of the final rule adopting this new regulatory provision. A rating period is defined in § 438.2 as a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS, and typically begins with a calendar year or a State's fiscal year. We indicated that the delay between the effective date of the final rule and the start of the next rating period would provide both States and the affected Medicaid managed care plans with adequate time to prepare both the necessary contract terms and finish the necessary administrative processes for creating and issuing enrollee identification cards with these newly required Medicaid-specific BIN, PCN, and group number identifiers.

This proposal was made under our authority in section 1902(a)(4) of the Act to specify "methods of administration" that are "found by the Secretary to be necessary for . . . proper and efficient operation." Having States require their MCOs, PIHPs, or PAHPs that provide CODs to Medicaid enrollees to add these types of unique identifiers to the enrollee identification cards would make the Medicaid drug program run more efficiently and improve the level of pharmacy services provided to Medicaid enrollees. With the inclusion of Medicaid-specific BIN, PCN, and group number identifiers on the enrollee

identification cards issued to the enrollees of MCOs, PIHPs, and PAHPs, pharmacies would be able to identify patients as Medicaid enrollees, and better provide pharmacy services. This would be helpful to all parties to ensure that Medicaid benefits are provided correctly, including confirming any accurate cost sharing amounts, along with helping to ensure that claims are billed and paid for appropriately.

This proposed change may help to reduce the incidence of 340B Program duplicate discounts by identifying Medicaid managed care plans. Section 340B(a)(5)(A) of the PHS Act prohibits duplicate discounts; that is, manufacturers are not required to both provide a 340B discounted price and pay the State a rebate under the Medicaid drug rebate program for the same drug.

Accordingly, we proposed to amend the regulatory language in § 438.3(s) to add paragraph (s)(7) to mandate that Medicaid managed care contracts require that Medicaid MCOs, PIHPs, and PAHPs that provide coverage of CODs assign and exclusively use unique Medicaid BIN, PCN, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits. We proposed that Medicaid managed care contracts must include this new requirement (which would require compliance by MCOs, PIHPs, and PAHPs) no later than the next rating period for Medicaid managed care contracts, following the effective date of the final rule adopting this new provision.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the use of unique Medicaid-specific BIN, PCN, and group number identifiers for managed care enrollees to ensure proper enrollee identification, application of benefits, and claims and billing processes, which would aid in reducing uncertainty and ambiguity with Medicaid prescribed drug claims. Commenters believe that this will help pharmacies identify patients as Medicaid managed care enrollees and support administration of appropriate Medicaid benefits. Some commenters also noted that many States report that they either already require unique BIN, PCN, and group identifier numbers or believe that this would be feasible to implement.

Response: We appreciate the support and agree that unique BIN, PCN, and group number identifiers on Medicaid managed care pharmacy identification

cards will be helpful in supporting the administration of the Medicaid program.

Comment: Several commenters supported adding the requirement that Medicaid managed care enrollee identification cards contain BIN and PCN numbers but suggested that the requirement should be for a BIN and PCN group combination, instead of requiring unique identifiers separately. These commenters recommended that CMS clarify that the requirement would be met by the inclusion of a unique combination of BIN, PCN, and group number identifiers on Medicaid enrollee identification cards to identify a patient as a Medicaid enrollee with coverage through a specific Medicaid managed care plan contract. Other commenters suggested that requiring unique BIN and PCN combinations for managed care Medicaid enrollees would be more effective.

Response: We agree that separate, unique BIN and PCN numbers would not be as effective as having a unique Medicaid-specific BIN and PCN combination, along with a group number identifier, to be issued for Medicaid managed care identification purposes. We understand that without having a unique BIN and PCN combination requirement, there could potentially be thousands of separate, individual new BINs and PCNs. Therefore, as we noted in the response to the previous comment, we are finalizing this requirement and are adding the term “combination” in this final rule so that a unique BIN and PCN combination, along with a group number identifier, will be assigned for Medicaid managed care enrollees’ identification cards.

Comment: Several commenters suggested that a list of unique Medicaid-specific BIN and PCNs with effective dates be publicly published and updated in a timely manner. One commenter requested that CMS publish the list by surveying States for unique BIN and PCN numbers used for Medicaid managed care enrollees and publishing a list of all such BIN and PCN numbers, similar to how HHS publishes lists of BIN and PCN numbers used to identify Medicare Part D beneficiaries. Additionally, one commenter suggested that Medicare and Medicaid standardize the process by which the BIN and PCN numbers are published, along with the publication of an up-to-date list of the unique BIN and PCN numbers.

Other commenters suggested that the States publish the lists on their websites, since they currently cannot be found in a centralized location. One of these commenters believes that the

creation of a publicly published list of numbers would aid States’ monitoring and oversight efforts for this plan requirement. This commenter also recommended CMS provide guidance on pharmacy point of sale (POS) operations to aid associated State monitoring and oversight.

Another commenter recommended that the BIN and PCN numbers be published on a list in machine readable form, mirroring how CMS publishes BIN and PCN numbers for Medicare Part D beneficiaries via various CMS web pages, such as the page entitled “Part D Information for Pharmaceutical Manufacturers.”⁷

Response: We appreciate the recommendations from the commenters concerning the publication of a list with unique BIN and PCN identification numbers; however, we decline to adopt these suggestions. Because States have the option of publishing a listing of their MCOs, PIHPs, and PAHPs with the related BIN and PCN combinations, along with the group number identifiers in any format on their websites, CMS defers to States to determine if they believe this would improve operations to include this information in one centralized location.

Comment: One commenter requested clarification on whether this requirement for unique BIN, PCN, and group number identifiers is applicable to Title XXI CHIP, State-funded programs in addition to Title XIX Medicaid.

Response: This regulation applies to Medicaid and CHIP managed care programs subject to the requirements in 42 CFR part 438 in Title XIX (Medicaid). This regulation does not apply to the separate CHIP programs operating pursuant to 42 CFR 457 in Title XXI (State Children’s Health Insurance Program). States may also choose at their option to consider a similar standard for State-funded programs.

Comment: Several commenters recommended changes to the applicability date for the requirement to include unique BIN, PCN, and group number identifiers on Medicaid managed care enrollee identification cards for pharmacy benefits. These commenters expressed concern with the proposed applicability date as they did not believe it was feasible to implement this requirement by the next rating period for Medicaid managed care contracts following the effective date of the final rule. Commenters indicated additional time was needed for necessary operational changes including

⁷ <https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers>.

information system development, configuration and testing as well as the creation of new enrollee identification cards and associated distribution to enrollees. Commenters varied in the recommended delay with timeframes with recommendations ranging from 12 to 18 months.

One commenter recommended that the applicability date be accelerated to implement the inclusion of BIN, PCN, and group number identifiers before the next contract rating period for managed care plans as the commenter believes this could prevent 340B duplicate discounts.

A few commenters were in support of unique BIN, PCN, and group number identifiers for each enrollee on Medicaid managed care enrollee identification cards but suggested that this requirement apply prospectively only to new Medicaid managed care plan contracts entered into or renewed after the effective date, as requiring mid-term contractual amendments would be disruptive and burdensome. They requested additional time sufficient for systems development, configuration, testing, PBM support, and card development. A commenter stated that many State Medicaid programs enter into multi-year contracts with managed care plans that may still be in effect by the time this rule is finalized.

Another commenter requested that as CMS finalizes an applicability date for this provision that it considers the need to update industry specifications that go through substantive, formal approval processes prior to a formal adoption by a standards-setting authority. The commenter suggested using existing standards and processes, when possible, for consistency between Medicare Advantage and Medicaid in the way these numbers are presented, if possible.

Response: We appreciate the issues raised concerning the timeframe for including Medicaid-specific BIN and PCN combinations, along with group number identifiers on enrollee identification cards for Medicaid managed care enrollees. We agree that additional time may be needed for all MCOs, PIHPs, or PAHPs to implement these requirements.

Therefore, we are finalizing the applicability date for this provision to be the first rating period for contracts with managed care plans beginning on or after 1 year following the effective date of this final rule.

Comment: A few commenters stated that the BIN definition, format, and field used in pharmacy claims transactions would be changing as of the next version of the Telecommunication Standards named under HIPAA. One

commenter noted that CMS recently proposed to update the NCPDP Telecommunication Standard in a proposed rule. The commenter stated that the proposal has not yet been finalized but is expected soon and will most likely require health plans to distribute new member enrollee identification cards during the implementation period. The commenter recommended that CMS should consider any unintended administrative impacts that could occur due to the timing of rule implementation and the resulting need to reissue enrollee identification cards.

Response: We appreciate the information that was shared regarding the upcoming changes to the Telecommunication Standards. As stated previously, we are extending the applicability date in this final rule for this provision to be the first rating period for contracts with managed care plans beginning on or after 1 year following the effective date of this final rule. We believe this additional time will allow States and managed care plans additional time to undertake the operational activities associated with this requirement, including any changes to the Telecommunication standards.

Comment: Multiple commenters supported the unique BIN, PCN, and group number identifier requirements and suggested additional policies to be developed to eliminate 340B Program duplicate discounts. Commenters believe that this provision will not fully address the risk of 340B duplicate discounts in Medicaid managed care and urged CMS to consider additional policies designed to avoid Medicaid and 340B Program duplicate discounts, including, but not limited to, a “carve out” approach, wherein drugs purchased under the 340B Program may not be furnished to Medicaid enrollees, a claim-level identification approach, and requiring the usage of 340B Program claims modifiers. Another commenter believes that if 340B covered entities disclosed to insurers when drugs administered to their enrollees (or prescriptions filled in contracted pharmacies) were purchased via the 340B Program, this would assist with the prohibition on duplicate discounts. Other commenters suggested that CMS should not allow providers to submit Medicaid claims until after completing a 340B eligibility screening and requiring States to provide detailed claim-level utilization data to manufacturers. One commenter recommended that comparable identifiers be used for medical benefit products.

A few commenters suggested requiring pharmacies to enter BIN, PCN, and group number identifiers at the point of sale, so that having the identification of a Medicaid managed care enrollee can signal to the pharmacy to append the NCPDP “20” submission clarification code so that the claim can be excluded from States’ invoices to manufacturers for Medicaid rebates. Other commenters stated that there are challenges with requiring a point-of-sale modifier for contract pharmacies. Other commenters noted that 340B determination of a prescription drug claim is not always known at the point of sale. They stated that 340B determination is often made retrospectively based on several factors, such as the replenishment model and batch reporting to a clearinghouse.

Multiple commenters stated that they oppose pharmacies being required to identify 340B claims either prospectively or retroactively, but support an alternative solution where third-party administrators provide 340B data to CMS. They also stated that there remains no requirement for pharmacies to implement a system to flag a claim as Medicaid.

Several commenters recommended clarity on the dispute resolution process to determine if the State or the covered entity is responsible for remedying a duplicate discount in a particular situation. Commenters suggested that CMS issue guidance to States to establish a transparent and consistent dispute resolution process to resolve issues regarding duplicate Medicaid/340B discounts between manufacturers and State Medicaid agencies. Commenters also stated that Medicaid managed care plans contracting with States, to help assure accountability on duplicate discounts, should be required to share data with manufacturers to permit identification of claims for which the drug was purchased under the 340B Program.

Other commenters encouraged CMS to work with the Health Resources and Services Administration (HRSA) to ensure that Medicaid managed care plan utilization is added to the Medicaid Exclusion File (MEF) as a way to establish a mechanism to track and avoid duplicate discounts on Medicaid managed care plan utilization. A few commenters suggested that it would be more appropriate for HRSA to require that “340B patients” receive enrollee identification cards for their 340B prescription drug benefits with this type of plan identifier information through their 340B covered entities.

Response: We believe that the new requirement for the inclusion of a

unique Medicaid-specific BIN and PCN combination, along with a group number identifier, may help States and their managed care plans avoid invoicing for rebates on 340B drugs by identifying which plans are covered under Medicaid. While we appreciate the comments received for additional ways to improve the operations of the 340B Program, these suggestions are outside of the scope of this final rule.

Comment: A few commenters expressed opposition to the exclusive use of unique Medicaid-specific identifiers on enrollee identification cards. Reasonings include that the addition of exclusive BIN and PCN numbers is insufficient policy action to reduce or eliminate 340B duplicate discounts and that the action is unduly burdensome and unlikely to have a meaningful impact on 340B duplicate discounts. One commenter requested that CMS allow for continued use of the existing identification numbers.

Another commenter stated that the inclusion of identifiers on enrollee identification cards could make it easier to engage in discriminatory reimbursement for 340B covered entity providers. They stated that such discriminatory reimbursement could have a negative effect on certain 340B covered entities. Other commenters requested that CMS not implicate pharmacies in the process of identifying and reconciling 340B claims.

One commenter was opposed to this BIN, PCN and group number identifier requirement since they believe the main purpose was to help States and managed care plans identify claims for drugs paid for under the 340B Program to help avoid duplicating discounts or rebates via the MDRP. For their managed care delivery system in which Medicaid managed care enrollees primarily access care from plans and contracted providers that do not participate in 340B, the commenter stated that there would be a significant operational burden to deploy new enrollee identification cards with BIN, PCN, and group number identifiers without a corresponding benefit.

Another commenter also stated that creating a unique BIN and PCN for each managed care plan would be unduly burdensome. They recommended amending this proposal such that this requirement would only apply to unique group number identifiers, and not BIN and PCN, on Medicaid managed care enrollee identification cards for pharmacy benefits. Other commenters recommended that Medicaid be consistent with the policy requiring Medicare Part D plan to use unique BIN and PCN combination identifiers, and

not include group number identifiers, to identify enrollees.

Response: We appreciate the concerns raised by the commenters but believe that mandating that States require their MCOs, PIHPs, and PAHPs that provide CODs to Medicaid enrollees to include a unique Medicaid-specific BIN and PCN combination, and group number identifiers, on the enrollee identification cards would make the Medicaid drug program run more efficiently, help avoid 340B duplicate discounts, and improve the level of pharmacy services provided to Medicaid beneficiaries.

Pharmacies' identification of patients as Medicaid enrollees based on the inclusion of Medicaid-specific BIN, PCN, and group number identifiers on the enrollee identification cards must not be used in any way to discriminate in the provision of healthcare services, and such alleged behavior may be referred to HHS' Office for Civil Rights or other authorities.

After considering the comments raised by the commenters, we are finalizing § 438.3(s) with some changes to the proposed regulatory text. We will modify § 438.3(s)(7) by: adding "combination," so that a unique BIN and PCN combination, and group number identifiers, will be assigned and used on enrollee identification cards; removing the comma after "(BIN)" and replacing it with "and" for grammatical correctness; and replacing "beneficiary" with "enrollee" to accurately acknowledge that enrollee identification cards are provided to a Medicaid beneficiary enrolled in a managed care plan in a given managed care program. Furthermore, we are revising the applicability date for this provision to be the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following the effective date of the final rule. To accomplish this, we are removing the proposed applicability date from § 438.3(s)(7) and establishing § 438.3(w) with this applicability date.

2. Drug Cost Transparency in Medicaid Managed Care Contracts

In the proposed rule, we included a provision that would require that the contracts between States and MCOs, PIHPs, and PAHPs that provide coverage of CODs require these managed care plans to structure contracts with any subcontractor, which may include for the delivery or administration of CODs, in a manner that ensures drug cost spending transparency by requiring the subcontractor to report separately certain expenses and costs. As part of our proposal, we noted that these subcontractors may include PBMs.

As stated in the preamble of the proposed rule, PBMs are intermediaries in the relationship between the managed care plans and the health care (medical and pharmacy) providers that provide CODs. That is, PBMs have contracts with both the managed care plans to administer the pharmacy benefit, as well as with the health care providers that administer or dispense drugs to patients that are enrolled in the managed care plan. Among other tasks in the marketplace, a PBM may be responsible for developing a drug formulary, collecting manufacturer rebates on behalf of the managed care plan, performing Drug Utilization Review (DUR), adjudicating claims, and contracting with retail community pharmacies and other health care providers to develop a network of providers that can dispense or administer drugs to managed care enrolled patients.

PBMs also may negotiate pharmacy reimbursement rates on behalf of the various health plans, including Medicaid managed care plans with which it contracts, to pay the pharmacy and other health care providers for the CODs that are dispensed or administered. In most cases, the pharmacy reimbursement rates are specified in the contract between the PBM and the pharmacy providers, and these include pharmacy reimbursement rates for brand name and generic prescription drugs, as well as the dispensing fees paid to dispense or administer the prescription drug. In addition, there are also administrative fees paid to the PBM by the managed care plans for its administration and operation of the pharmacy benefit.

The margin between the amount charged by the PBM to a managed care plan for a COD and the amount paid by the PBM to a pharmacy provider is referred to as the "spread," and this construct is referred to as "spread pricing." A detailed description and example of how spread pricing works and how it may affect Medicaid spending for prescription drugs was included in the proposed rule at 88 FR 34250 thru 34251. The amount of this margin or "spread" may only be known by the PBM, unless a State Medicaid program or managed care plan specifically requires the disclosure of the charge and payment data that are used to make these calculations. This information deficit results in a lack of accountability and transparency to the Medicaid managed care plans, and thus the Medicaid program, which we believe is contrary to proper and efficient operation of the State Medicaid program, and potentially creates

conflicts of interest in connection with payment for CODs. Spread pricing can increase Medicaid pharmacy program costs, reduce efficient operation of the Medicaid program, and reduce the transparency of State Medicaid expenditures within managed care programs.

We further noted in the preamble to the proposed rule that section 1902(a)(4)(A) of the Act requires that the State plan for medical assistance comply with methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the State plan. Greater transparency and accountability by Medicaid managed care plans (and their subcontractors) to the States for how Medicaid benefits are paid compared to how administrative fees are paid, are both necessary for efficient and proper operation of Medicaid programs. Moreover, this lack of transparency makes it more difficult for States and Medicaid-managed care plans to ensure that the plan's Medical Loss Ratio (MLR) calculation is limited to the true medical costs associated with the provision of CODs. We noted that MLR calculations are used as part of capitation rate development. Capitation rates are paid to Medicaid managed care plans; thus, their accuracy is critical in assuring that Medicaid payments are reasonable and appropriate. We further noted that managed care capitation rates must (1) be developed such that the plan would reasonably achieve an 85 percent MLR (§ 438.4(b)(9)) and (2) are developed using past MLR information for the plan (§ 438.5(b)(5)). In addition to other standards outlined in §§ 438.4 through 438.7, requirements related to accurate MLRs are key to ensuring that Medicaid managed care capitation rates are actuarially sound. In addition, Medicaid managed care plans may need to pay remittances to States should they not achieve a specific MLR target when a remittance is required by a State. Thus, the accuracy of MLR calculation is important to conserving Medicaid funds.

We also pointed out that CMS issued a Center for Medicaid & CHIP Services (CMCS) Informational Bulletin on May 15, 2019, for States and Medicaid managed care plans, titled "Medicaid Loss Ratio (MLR) Requirements Related to Third Party Vendors" ("2019 CIB") (see <https://www.medicare.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib051519.pdf>), specifying MLR data collection requirements when a managed care plan uses subcontractors for plan activities. The 2019 CIB provided additional guidance, including an example regarding the MLR data

collection requirements when third party vendors, such as PBMs, are involved. However, while the 2019 CIB uses PBM spread pricing as a specific example, there was nothing currently in Federal regulation that specifically detailed contract requirements that (non-claim) administrative costs, fees, or expenses of a managed care plan's subcontractor should not be counted as incurred claims for purposes of the managed care plan's MLR calculation.

In addition, the preamble to the proposed rule discussed that the Medicaid managed care regulation at § 438.230(c)(1) requires that certain agreements are to be included in subcontracts, including that subcontractors agree to perform the delegated activities and reporting responsibilities in compliance with the managed care plan's contract obligations, and that the reporting standards at § 438.8(k)(3) specify that managed care plans must require any third-party vendor providing claims adjudication activities to provide all underlying data associated with MLR calculation and reporting. The 2019 CIB explained how these regulatory obligations require that all subcontractors that administer claims for the managed care plan must report the incurred claims, expenditures for activities that improve health care quality, and information about mandatory deductions or exclusions from incurred claims (overpayment recoveries, rebates, other non-claims costs, etc.) to the managed care plan and that the requirements and definitions in § 438.8 for these categories of costs and expenditures must be applied to the required reporting.

For these reasons, we proposed to amend § 438.3(s) to require MCOs, PIHPs, and PAHPs that provide coverage of CODs to structure any contract with any subcontractor for the delivery or administration of the COD benefit to require the subcontractor to report separately the amounts related to: (i) The incurred claims described in § 438.8(e)(2) such as reimbursement for the covered outpatient drug, payments for other patients services, and the fees paid to providers or pharmacies for dispensing or administering a covered outpatient drug; and (ii) Administrative costs, fees and expenses of the subcontractor. We noted that this proposal will not change the applicability of the 2019 CIB to PBM subcontractors or to other subcontracting arrangements used by a Medicaid managed care plan; the 2019 CIB remains CMS' position on how §§ 438.8 and 438.230 apply.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the requirement that managed care plans separately report the amounts for incurred claims for CODs and not include administrative costs in the MLR numerator, and by doing so, this new requirement would provide transparency to help identify PBM spread pricing practices that potentially lead to pharmacies being underpaid for their services. Other commenters, while supporting the proposal, questioned why spread pricing is not entirely prohibited.

Response: We appreciate commenters' support regarding the regulation as proposed. We note that CMS does not have the authority under Federal Medicaid statute to prohibit a PBM's practice of spread pricing. However, we believe this regulation, once final, will provide greater transparency to State Medicaid agencies and managed care plans regarding how the PBMs are spending the payments that are made to them by the Medicaid managed care plan to administer the Medicaid prescription drug benefit. We believe this information will help to inform the State's decision-making relating to the administration of the prescription drug benefit. It will also help the Medicaid managed care plans have more accurate data to calculate their MLRs, as well as ensure that States can accurately develop capitation rates. Finally, it will help States and managed care plans ensure that PBMs are being appropriately compensated for their services by requiring that the subcontractors report separately incurred claims for CODs and administrative fees, costs, and expenses in sufficient detail and the level of detail must be no less than the reporting requirements in 42 CFR 438.8(k).

Comment: With respect to CMS' proposal to separate the amounts related to incurred claims (for example, COD reimbursement and dispensing fees) from a PBM's administrative fees, commenters urged CMS to also consider downstream impacts in the supply chain. The commenters indicated that to support robust pharmacy market competition and lower health care costs for beneficiaries, CMS must ensure that pharmacies and other health care providers' proprietary information, such as the pharmacy reimbursement (dollar amount) is not disclosed and cannot be traced back to an individual pharmacy. The commenters also indicated that they understand the difficulty in balancing both promoting market

competition and striving for greater transparency in the marketplace; however, these commenters noted this balance could be achieved with transparent accountability measures and comprehensive PBM reform.

Response: We continue to believe this requirement will not deter market competition because it does not require public disclosure of provider-specific proprietary information. Instead, § 438.3(s)(8) will require that the managed care plans contract with the subcontractor will require the subcontractor report separately incurred claims and administrative costs, fees and expenses of the subcontractor necessary for the managed care plan's reporting of the MLR consistent with the requirements at § 438.8(e)(2). The reporting must be in sufficient detail to allow a managed care plan to accurately incorporate the expenditures associated with the subcontractor's activities into the managed care plan's overall MLR calculation. As provided in the 2019 CIB, the level of detail must be no less than the reporting requirements in 42 CFR 438.8(k), but may need to be more if necessary to accurately calculate an overall MLR or to comply with any additional reporting requirements imposed by the State in its contract with the managed care plan. We note that there is nothing in the regulation that prevents the subcontractor from negotiating terms limiting the identification of provider-specific expenditures in the contract with the managed care plan, as long as those terms are consistent with the requirements of this final rule and other Federal contract requirements in regulation at 42 CFR part 438.

Comment: Many commenters requested that CMS implement Federal requirements on PBMs' arrangements with pharmacies rather than just focus on contracting requirements between the managed care plans and PBMs. The commenters encouraged CMS to consider issuing rulemaking that would enhance pharmacy network adequacy, ensure reasonable reimbursement for pharmacies, require certain payment models for managed care plans that cover CODs, and promote payment parity between PBM affiliated and non-affiliated pharmacies in Medicaid managed care. Other commenters suggested including data quality controls, alignment with other payer models, and limitations of reimbursements to non-PBM affiliates. Specifically, commenters requested that CMS revise § 438.3(s)(8) to:

- Require managed care plans eliminate spread pricing, such as by requiring the plans to utilize certain

payment models with their PBM subcontractors which dictate how much the PBM is paid for their administrative activities and require specific payment models of how much providers and pharmacies are paid. The commenter also pointed to its support of current proposed Federal legislation (S. 1038, Drug Price Transparency in Medicaid Act of 2023/HR 3561, the PATIENT Act) that includes similar proposals that would ban spread pricing in Medicaid.

- Require that managed care plans' contracts with their subcontracted PBMs require reimbursement for all in-network pharmacies in the managed care program based on a transparent benchmark of National Average Drug Acquisition Cost (NADAC), or WAC when there is not a NADAC price, for a Medicaid COD with a commensurate dispensing fee comparable to the State's Medicaid survey-based fee-for-service PDF as a final payment, absent written proof of fraud. The commenter also suggested that CMS should require that the managed care plan only include these claim cost payments paid by the PBM to the pharmacy for the managed care plan's reported MLR to a State Medicaid program.

- Prohibit managed care plans and their subcontracted PBMs from reimbursing non-PBM affiliated pharmacies less than PBM-owned or PBM-affiliated pharmacies.

The commenters expressed their belief that by adding these provisions to the proposed regulations, CMS would take important steps to eliminate the managed care PBM practices that the commenter indicates have led to nearly \$1 billion in Medicaid fraud settlements by 17 States against managed care plans for overbilling Medicaid programs for managed care prescription benefits.

Response: We are aware of the settlements between PBMs and States, and the potential that such spread pricing arrangements will result in overbilling Medicaid. We believe that § 438.3(s)(8), which will require the subcontractor report to the managed care plan separately incurred claims (for example, covered outpatient drug reimbursement) from administrative costs, fees, and expenses for purposes of calculating the managed care plan's MLR, will likely impact the practice of PBM spread pricing. That is, greater transparency to the States of how prescription expenditures are being allocated by the PBMs contracted with the Medicaid managed care plans to provide pharmacy benefits may reduce the likelihood that the PBM will engage in spread pricing.

Furthermore, we are aware of actions taken by individual States at their

option to end or limit impact of PBM spread pricing, including in Medicaid. However, as noted in the preamble, we do not believe we have Federal authority to prohibit spread pricing. Nonetheless, we believe that this final rule will provide greater transparency to State Medicaid agencies and Medicaid managed care plans to help inform the State's decision-making relating to the administration of the prescription drug benefit and improving accuracy of plans' MLR calculations.

With regards to pharmacy reimbursement, the adequacy of reimbursement by managed care plans or their subcontractors to their network or non-network pharmacies or providers is out of scope of this final rule. Furthermore, CMS does not have authority to impose on Medicaid managed care plans the State plan requirements at § 447.518, which require State Medicaid FFS payment methodologies for retail community pharmacies be in accordance with the definition of actual acquisition costs at § 447.502, including requiring the use of an Actual Acquisition Cost (AAC) benchmark in setting prescription drug reimbursement at the retail level. These regulations do not apply to Medicaid managed care plan payments to pharmacies or providers for CODs.

We note that if a State or CMS finds that a Medicaid managed care plan does not have a sufficient network of pharmacies or providers to ensure enrollee access to prescription drug benefits, the States and CMS can engage with the Medicaid managed care plans on whether the reimbursement to pharmacies and/or providers for prescription drugs is adequate to attract pharmacies/providers in their network and ensure Medicaid beneficiaries have access to the Medicaid prescription drug benefit. We remind States of their obligation to develop and enforce a quantitative network adequacy standard for pharmacies at § 438.68(b)(1)(vi).

Comment: One commenter suggested that CMS urge PBMs to disclose and document their profit usage and accounting for when profit is used to augment beneficiaries' drug access. This same commenter questioned CMS' position on PBMs charging insurers higher than what they pay pharmacies, and recommended CMS investigate the efficacy of using PBMs for negotiating reduced drug prices.

Response: We may consider the commenter's concerns in future policy development. Otherwise, the use of a PBM's profits and investigation of PBM practices are not a subject of this final rule.

Comment: Several commenters expressed their belief that increasing the level and detail of reporting by PBMs is a good first step in increasing transparency; however, they noted more could be done to protect the intent and the efficacy of the 340B Program and its eligible covered entities by not allowing PBMs to use discriminatory practices, such as PBM payment cuts, that harm hospitals and community health centers that are 340B covered entities and possibly jeopardize patient access to 340B covered entities and contract pharmacies. The commenters indicated that this would allow the savings generated through the 340B Program to be passed along to the PBM to increase their profits. The commenters supported provisions addressing the contracting between PBMs and managed care plans but do not support any policies that will impact a pharmacy's reimbursement.

Response: The efficacy of the 340B Program and any discriminatory practices of PBMs is out of scope of this final rule. Furthermore, as stated earlier, the adequacy of reimbursement by a plan (via its PBM) to a managed care plan's network or non-network pharmacy, which could be a covered entity, is also not a subject of this final rule, nor is the effect of PBM practices on 340B entities and use of 340B savings.

Comment: Several commenters supported the proposed changes, including the information subcontractors of managed care plans need to separately identify (separately identify incurred claims from administrative costs, fees, or expenses) and provide to managed care plans, but requested that CMS develop detailed guidance on the specific cost elements to be reported and a reporting template to ensure standardization and ease of adoption. They indicated that it would be helpful for CMS to indicate the specific parameters that would be included in this requirement to provide greater transparency into PBM and pharmacy services administrative organizations (PSAOs) and any other subcontractor that has incurred claims on behalf of the managed care plan associated with covered outpatient drug coverage.

Response: We appreciate the commenters' request for more detailed guidance. We will evaluate if additional guidance is needed as part of implementation efforts for this requirement and will take these suggestions into consideration as part of that evaluation.

Comment: One commenter indicated that its State currently requires its managed care plans to produce reports

with claim level data on the payment made to the PBM by its managed care plans and the amount of payment the PBM has paid to the pharmacy. In addition to claim level data, the commenter indicated that this State requires its managed care plans to report on all payments, including administrative fees, to and from the PBM, managed care plan, and pharmacies at an aggregate level. The commenter believes additional Federal requirements would strengthen States' abilities to secure data around drug costs. Another commenter further pointed to the National Academy of State Health Policy (NASHP) website, in which NASHP analyzed PBM contracts in a subset of States and developed model contract language to address the lack of transparency and promote cost-saving incentives in typical PBM contracts.

Response: We appreciate the commenter's support for finalizing § 438.3(s)(8). We do not intend to further revise the Federal requirements in § 438.3(s)(8) at this time. We encourage States to assess if they wish to impose additional reporting requirements on plans or their subcontractors to facilitate State priorities such as those on transparency and payment, or develop model contract language for plans to utilize with their subcontractors.

Comment: One commenter suggested that CMS consider alignment with other payer models for drug cost data collection, such as the Prescription Drug Data Collection (RxDC) required by the Consolidated Appropriations Act of 2021. The commenter noted that alignment would facilitate the ability of managed care plans to provide cost transparency, minimize burden, and improve the ability of CMS to compare drug costs across delivery systems.

Response: We appreciate the commenter's suggestion that we align Medicaid data collection efforts from payers with other data collection programs, such as the RxDC, especially for purposes of transparency. However, the data collection required under this provision is distinct from the RxDC program and serves to ensure a Medicaid managed care plan has the data it needs from its subcontractors to accurately calculate and report its MLR.

Comment: A few commenters requested clarification regarding the applicability date for § 438.3(s)(8) and urged CMS to grant managed care plans and their subcontractors sufficient time, such as 6 months or more, to allow for necessary operational, system, and contracting changes.

Response: The applicability date for § 438.3(s)(8) as finalized is no later than the State's first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year from the effective date of this final rule. As part of this final rule, we have added § 438.3(w) to finalize this applicability date.

Comment: One commenter requested that spread pricing information be made public where possible, stating it is vital to the public's interest to understand what the cost of PBMs are to Medicaid and enrollees.

Response: We assume that the commenter is requesting that CMS and/or States publicly publish the information collected by the managed care plans from PBMs that distinguish the PBM's payment for the drug and the administration fee and how much the managed care plan paid the PBM for such services. This final rule does not modify the elements States are required to include in their MLR summary reports to CMS under § 438.74; therefore, CMS will not have routine access to PBM payment information that is provided by PBMs to managed care plans and cannot release it to the public. States may consider additional steps, such as what level of data they wish to compile from plans and their subcontractors, in addition to those required for reporting in accordance with § 438.74 and associated transparency on the State's public website.

Comment: A few commenters acknowledged that, making PBMs break out their costs would give State Medicaid programs a better sense of whether spread pricing is occurring, but commenters suggested a more effective approach would be to prohibit spread pricing in Medicaid managed care. They noted that the Congress is currently considering numerous bills related to PBM practices and could include a prohibition of spread pricing in Medicaid managed care as part of those efforts.

Response: We appreciate the support for this final rule. As noted previously, we do not have the authority to completely prohibit these PBM practices.

Comment: One commenter requested clarification on the separate identification of a COD, if a COD is deemed to be eligible for a MDRP rebate. The commenter supported a requirement that if a Medicaid managed care plan contracts with any subcontractor for the delivery or administration of CODs, the managed care plan must require the subcontractor to separately identify CODs, even if the

CODs are reimbursed as a bundled payment.

Response: As specified in § 438.3(s)(8), we are finalizing a requirement for Medicaid MCOs, PIHPs, and PAHPs that provide coverage of CODs to require any subcontractor for the delivery or administration of the COD benefit to report separately the amounts related to the incurred claims described in § 438.8(e)(2), such as reimbursement for the CODs, from the administrative costs, fees, and expenses of the subcontractor. The separate reporting requirement for the delivery or administration of the covered outpatient drug benefit under § 438.3(s)(8) is not limited to those instances when the COD benefit is paid separately as a claim; the separate reporting requirement applies regardless of the COD benefit reimbursement methodology (for example, bundled payment for a specific service).

After consideration of public comments on this provision, we are finalizing § 438.3(s) with some changes to the proposed regulatory text. While we discussed in the preamble of the proposed rule that this would apply to MCOs, PIHPs, and PAHPs, we did not include the phrase “MCO, PIHP, or PAHP” in the regulatory text. Thus, we will modify § 438.3(s)(8) by adding at the beginning of the paragraph the phrase “The MCO, PIHP, or PAHP” to conform with the other paragraphs in § 438.3(s), inserting “must” to replace “to” for additional clarity, and inserting “to the MCO, PIHP, or PAHP” for clarity on the entity that the subcontractor reports the required information to. We also are adding § 438.3(w) to include an applicability date for the requirements of paragraphs (s)(7) and (s)(8), which will be the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year following November 19, 2024.

C. MDRP Administrative and Program Integrity Changes

1. Definitions (§ 447.502)

a. Modification to the Definition of Covered Outpatient Drug (§ 447.502)

In the proposed rule, we proposed to modify the definition of a COD. We noted as background that sections 1927(k)(2) and (3) of the Act provide a definition of the term “covered outpatient drug” (COD) and a limiting definition, which excludes certain drugs, biological products, and insulin provided as part of, or as incident to and in the same setting as, enumerated services and settings from the definition of COD. This exclusion is subject to a parenthetical, however, which limits the

exclusion to when payment may be made as part of payment for the enumerated service or setting, and not as direct reimbursement for the drug. In other words, a product that would otherwise qualify as a COD, is excluded from the definition if it is administered in certain settings and not directly reimbursed.

We also noted that in the 2016 COD final rule, we finalized a regulatory definition of COD in § 447.502 that substantially mirrors the statutory definition. Consistent with section 1927(k)(3) of the Act, the regulatory definition includes a limiting definition in paragraph (2) that excludes from the definition of COD any drug, biological product, or insulin provided as part of or incident to and in the same setting as anyone in a list of services, and for which payment may be made as part of that service instead of as a direct reimbursement for the drug.

We noted in the proposed rule that, over the years, we have received questions about when a payment is considered to be a direct reimbursement for a drug, and whether identifying a drug separately on a claim for payment may qualify as direct reimbursement for a drug. Such situations would render the drug eligible for rebates under section 1927 of the Act as a COD, or in other words, the limiting definition exclusion would be inapplicable in certain circumstances. We had proposed that, if a drug and its cost can be separately identified on a bundled claim for payment, and the identified amount attributable to the drug is made solely for the drug (and no other services), it can be considered direct reimbursement for the drug. Therefore, we indicated that direct reimbursement may be reimbursement for a drug alone, or reimbursement for a drug plus the service, in one inclusive payment if the drug plus the itemized cost of the drug is separately identified on the claim. The payment for the drug is not required to be a distinct, separate payment for such payment to be considered direct reimbursement.

Specifically, we proposed to amend the regulatory definition of the term covered outpatient drug at § 447.502 to add that direct reimbursement for the drug includes situations in which a claim for an all-inclusive payment identifies the drug plus the itemized cost of the drug.

Additionally, to support our proposal, we noted that the limiting definition in section 1927(k)(3) of the Act includes the following parenthetical: “. . . (and for which payment may be made under this subchapter as part of payment for [certain services] and not as direct

reimbursement for the drug).” The definition of the term covered outpatient drug in § 447.502 includes similar limiting language in a parenthetical at paragraph (2): “. . . (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug).” We noted that there was no meaningful distinction between the statutory and regulatory parenthetical language for purposes of the MDRP, and thus, we proposed to make a technical change by modifying the regulatory language so that it more closely mirrors the statutory language. We proposed to add “payment for” after “and for which payment may be made as part of” and to delete “instead of as a” in the limiting definition of covered outpatient drug and replace it with “and not as”.

The proposed definition would then read, in significant part, as “. . . (and for which payment may be made as part of payment for that service and not as direct reimbursement for the drug).”

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments supporting the proposed definition of direct reimbursement with respect to the COD’s limiting definition. Some comments provided general support for the proposed definition. One commenter stated that the definition will help ensure that Medicaid beneficiaries with a rare disease continue to have access to affordable outpatient drugs. Another commenter stated that the change will help ensure that States receive the MDRP rebates to which they are entitled, allowing providers to make treatment decisions based on the individual clinical circumstances of a patient. One commenter supported the definition and noted that current claims processing standards support the ability of a claim to contain the required information so that rebates may be billed. One commenter supported the definition and stated they believe that the modification to the definition reflects our current policy, and they requested clarification to confirm that understanding.

Response: We appreciate the support for the modification of the definition of a direct reimbursement as it relates to the definition of a COD. The modification to the definition was not intended to be a departure from current practice or in conflict with the current regulation or statute. Rather, the modification was intended to address the fact that States are now using newer reimbursement methodologies where it is not entirely clear whether drugs

reimbursed through that new methodology are CODs. As discussed subsequently, we are also adding clarifying language to ensure that our intention is clear that the definition does not inadvertently include drugs that do in fact meet the statutory limiting definition of COD.

Comment: We received several comments that are outside the scope of this rule. One commenter stated that the modified definition of COD would affect the covered entities that participate under the HRSA 340B Program because they use our definition of COD to determine if a drug is subject to 340B pricing. One commenter stated that CMS fails to convey how medical research and development will be protected with the proposed revisions. A few commenters noted that the modified definition of COD would increase the number of CODs subject to rebates which may make it difficult for manufacturers to continue to offer their drugs in Medicaid.

Response: Because these 340B issues are outside the scope of this rule, we are not addressing them. We appreciate the commenters' concern regarding the modification of the definition of COD and the increased number of CODs subject to rebates. While we do not believe this clarification to the definition will result in a significant change in the number of CODs, it may increase the number of instances where a COD may qualify for rebates. With respect to impact on research and development, this proposal will clarify for States when a drug is a COD and thus subject to rebates in some instances, and thus may result in States collecting rebates in circumstances where they are not currently collecting any rebates. As a result, States may take these clarifications into account when determining coverage and reimbursement policies for particular drugs. The impact of these clarifications may result in States having a net reduction in cost for these drugs, which may increase access to these drugs, and in turn, support manufacturers' research and development efforts. CMS does not believe that the clarification of the definition of a COD in this rule indicates that scientific drug development is not valued or that the definition will disincentivize the scientific development. The United States pharmaceutical market is the largest in the world, with a strong record of fostering innovation, and Federal health care programs are large payers for medications in the United States, supporting incentives for manufacturers to continue to develop

innovative medicines and make drugs available in the Medicaid program.

Comment: We received many comments stating that our proposed clarification of the term "direct reimbursement" conflicts with the language of the statute. Commenters also stated that the proposed revision would represent a significant and impermissible change to the meaning of the limiting language in the COD definition and stated that it would render language in the statute unnecessary. Commenters pointed to legislative history, assertions made by HHS in litigation that "a drug is not a covered outpatient drug if it is provided, and paid for, as part of a bundled service," language in the 2016 COD final rule, and responses in an FAQ published under the 2016 COD final rule to support their position that CMS historically considered that a drug was not a COD unless the drug was separately reimbursed. One commenter cited the following language from the 2016 COD final rule to support their position: "a drug which is billed as part of a bundled service with, and provided as part of or incident to and in the same setting as the services" [will only qualify as] a COD if "the State authorizes and provides a direct payment for the drug, consistent with the applicable State plan, separately from the service."

Response: Upon review of these comments, we are clarifying for States the situations in which they will be able to bill for a rebate for a COD that is directly reimbursed as part of a bundled or inclusive payment. Specifically, we are clarifying the term "direct reimbursement" as we agree that the proposed regulatory definition may not have clearly identified those situations that will qualify as direct reimbursement. In this final rule, we are adding language to the regulatory definition to indicate that direct reimbursement includes reimbursement for a drug that is part of an inclusive payment when the inclusive payment includes an amount attributable to the drug, the number of units of the drug that were dispensed or administered to the patient, and the amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the State plan.

Comment: Several commenters disagreed with CMS' assertion that the proposed modification to the definition of COD is a clarification of existing policy on the application of the limiting definition. They stated that rather than a clarification, they view the modification as a policy change with no

presented rationale. Commenters also stated that CMS' proposal is a departure from the agency's longstanding policy that no Medicaid rebate liability attaches to units reimbursed via bundled payments. Commenters also stated that our definition marks a significant and unacknowledged departure from the agency's longstanding approach to manufacturer rebate liability. A commenter mentioned that a basic requirement of the Administrative Procedure Act is that an agency must acknowledge that "it is in fact changing its position" and provide good reasons for any change in policy. They stated that CMS failed even to acknowledge its changing position and was, therefore, acting in an arbitrary and capricious manner. A few other commenters referenced language in the preamble to the 2016 COD final rule, when CMS previously stated, "if the drug is provided as part of a bundled service and not separately reimbursed, then the drug does not qualify as a [covered outpatient drug], in accordance with section 1927(k)(3) of the Act and is not subject to rebates."

Response: Our intent in the proposed rule was to provide clarification regarding when a payment represents direct reimbursement for a drug. Essentially, we were clarifying that, as used in the quoted language, "not separately reimbursed" in the context of bundled rates means not separately identified or itemized, with an amount associated with payment for the drug. Based on the comments, we agree that our proposed modification to the definition could be further clarified. In the past we have stated that no rebate liability attaches to drugs that are paid for as part of bundled payments. As just noted, this was intended to address situations in which an amount paid for a COD is not identified or itemized. As noted in the preamble to the proposed rule, interested parties have requested that we define situations in which rebates can be billed for drugs that are part of inclusive payments if the quantity of drug dispensed or administered can be identified. As noted in the response to previous comments, we are modifying the definition of direct reimbursement in this final rule to make it clear that, for rebates to be billed, the inclusive payment must include an amount directly attributable to the drug, and the amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the State plan.

Comment: We received some comments indicating that the proposed change to the definition of COD would

nullify the distinction between direct reimbursement and reimbursement made as part of a bundled payment. Commenters stated that “direct reimbursement” cannot be construed to mean “separately identified” without there being a distinct payment for the drug. Commenters also indicated that CMS failed to acknowledge that where a drug has been paid for as part of an indivisible payment for the drug and its associated services, Medicaid, by definition, has not directly reimbursed for the drug, and there is no “direct” throughline between the reimbursement amount and the payment associated with any one of the bundled items or services. Some commenters also stated that the proposed change ignores what they consider to be a reasonable interpretation of direct reimbursement.

Response: We agree that the proposed revision to the definition of COD regarding direct reimbursement did not adequately reflect that the amount of reimbursement for the drug should be tied to the State’s approved reimbursement methodology for that drug. We have therefore added language to the definition in this final rule to indicate that in order for the payment for the drug to be treated as direct reimbursement, the payment methodology for the inclusive payment must identify an amount directly attributable to the drug, such that the amount paid is based on a reimbursement methodology that is included in the applicable section of the State plan.

Comment: We received a few comments that because our modified definition of COD provides that drugs administered in an inpatient setting could be included in the definition of “covered outpatient drug,” we give no meaning to the word “outpatient” contained within the term.

Response: The term “covered outpatient drug” is a statutory term of art. The limiting definition in section 1927(k)(3) states that the term COD does not include any drug provided as part of, or as incident to and in the same setting as “inpatient hospital services,” among others, and for which payment is not made as direct reimbursement for the drug. If the Congress had intended for the statutory term of “COD” to be limited to the outpatient setting only, the limiting definition would be superfluous as applied to being included in inpatient hospital services. Because statutory interpretation principles hold that an agency should not construe a statute in a manner that renders a provision to have no effect, we disagree that the term COD is limited to drugs dispensed or administered in an

outpatient setting. Based on the plain text of 1927(k)(3), the term COD excludes a drug provided in the inpatient hospital setting only if the drug is provided as part of or as incident to and in the same setting as inpatient hospital services and for which payment is made as part of such services and not as direct reimbursement for the drug. We proposed to amend the regulatory definition of COD in a manner consistent with the statutory definition of this term of art to provide greater specificity as to when a drug provided in the inpatient setting is subject to the limiting definition and does not qualify as a COD.

Comment: A commenter noted that the statute focuses on the manner of payment, not the manner in which the provider’s costs are reflected on the claim, and that our proposed definition was only focusing on how the claim was submitted.

Response: We agree that the definition should include language about the manner of payment, which we understand to mean how the claim is reimbursed, and not only based on the information submitted on the claim. We have therefore revised the proposed definition to include language about the manner of payment, including that the payment methodology for the inclusive payment must include an amount directly attributable to the drug, such that the amount paid is based on a reimbursement methodology that is included in the applicable section of the State plan.

Comment: Several commenters noted that when payments for new and innovative therapies (cell and gene therapies, for example) are reimbursed in a payment that is bundled with a service (for example, under the Diagnosis-Related Group (DRG) system), the reimbursement is often insufficient for the drug and potentially results in lack of patient access to these new therapies. The commenters noted that conversely, some States are reimbursing the hospital separately for their acquisition cost of certain new and innovative drugs from their inpatient services associated with administering the drug, and such methods of direct reimbursement are adequately reimbursing providers/hospitals and encouraging patient access.

Response: We note that section 1902(a)(30)(A) of the Act requires States to ensure that “payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in

the geographic area.” The payment methodology for a COD must be identified in the State Plan and meet the foregoing standard. Some States already have approved methodologies outlined in their State plan that results in the ability for the State to collect rebates on some inpatient drugs. If a State plan does not address a distinct reimbursement methodology for a drug included in a bundled payment, then a SPA would need to be submitted and approved that includes such methodology in the appropriate section of the State plan.

Comment: One commenter stated that manufacturers have launched certain products assuming there would be limited MDRP rebates given the products are included in a bundled payment arrangement and altering this will lead to significant operational challenges, unsustainable pricing expectations, potential drug shortages, and compromised utilization within Medicaid.

Response: Again, we note that our intent for this clarification is to help manufacturers and States better understand how the term direct reimbursement for a drug will be applied with respect to the limiting language within the COD definition. Our review of comments alerted us to the fact that the proposed definition, as originally written, may be open to multiple interpretations. As a result, in response to such comments, we have modified the definition in this final rule to be clearer about when a payment is a direct reimbursement for a drug. Given the revisions, we do not believe that the challenges cited by the commenter will occur. We also note that there are States whose current Medicaid reimbursement policies account for carved out inpatient drugs for separate payment. These payment models have been intact for years and we do not have evidence that these payment models lead to significant operational challenges, unstable pricing expectations, drug shortages, or compromised Medicaid utilization. We also intend to provide additional guidance to States with respect to how the interpretation of direct reimbursement may be operationalized so that States can invoice for rebates for these CODs.

Comment: A few commenters expressed their concerns regarding drug manufacturers’ lack of access to claims level data for purposes of validating rebate invoices if CODs are merely identified or itemized and not separately reimbursed. One commenter stated that neither CMS nor States nor manufacturers have visibility into all payer claims to be able to ascertain how

bundled drugs and associated items and services are itemized. Manufacturers would have to obtain the billing document to verify the validity of rebate invoices. Another commenter stated that it was unclear that States would have the mechanism to collect such claims data for bundled drugs and present to manufacturers if requested.

Response: Manufacturers are always able to work with States to verify a claim for a Medicaid rebate. States will need to determine how they instruct their providers and managed care plans to identify for rebate billing purposes those inclusive payment claims where direct reimbursement is being made for a COD. This will allow States to include the COD in the rebate billings, as well as identify for Medicaid managed care plans such claims that they will have to report to the States for rebate billings.

For States that choose to reimburse these drugs separately, the State will have the information submitted on the claim identifying the drug and the number of dispensed or administered units of the drug. For States that choose to use a bundled reimbursement model that separately identifies the drug and takes the cost of the drug into account in the reimbursement as outlined in the methodology in the State plan, those States will also have sufficient information to identify the drug and the number of dispensed or administered units of the drug. This claim information will allow the State to provide utilization information to the manufacturer in order for the manufacturer to verify that utilization. Collection of the data and how it may be presented to manufacturers may vary by State or manufacturer.

Comment: Several commenters stated that finalizing the COD definition as proposed would subject some drugs (for example, cell and gene therapies to new rebate requirements and would undermine efforts to offer value-based payment models and innovative payment arrangements.

Response: All CODs, including cell and gene therapy drugs that are CODs for which the manufacturer has a rebate agreement, are subject to basic minimum Medicaid rebate requirements, regardless of whether they are provided as part of a value-based purchasing arrangement. As noted previously, some States have already received approval for a State plan amendment to carve out drugs, such as cell and gene therapy drugs from inpatient hospital payment rates, and reimburse them separately, thus allowing them to collect rebates. Further, the Cell and Gene Therapy Access Model being tested by the CMS

Innovation Center will require participating States to carve model cell & gene therapy drugs out of an inpatient payment bundle if the States want to participate in the Model so that the States may collect rebates on the drugs. With the clarification to the definition of direct reimbursement, as finalized in this rule, States may also bill for rebates for drugs that are provided as part of inclusive payments if they are itemized on the provider's bill, the number of units dispensed are identified, and the drug is paid according to the State's approved plan methodology for the drug. With these clarifications, we also believe that manufacturers and States may still pursue enhancements in patient access, equity, and health outcomes by executing VBP agreements and supplemental rebates for any COD per the State plan.

Comment: A few commenters stated that the cost of a drug has not necessarily been included in the development of a bundled payment rate for the underlying service. One commenter stated that a DRG-based payment for a hospital inpatient stay does not provide reimbursement for any one item or service involved in the bundle. Instead, the commenter stated that bundled payment rates are meant to reimburse generally for the collection of various items and services that may or may not be necessary to the delivery of care for a specific illness, procedure, or condition. The commenter noted that, typically, when DRG rates are used to reimburse providers, the payment is a predetermined amount that does not change based on the cost or amount of a specific drug that is administered or dispensed to the patient.

Response: We recognize that DRG is a commonly employed bundled payment methodology for an inpatient stay for a procedure or diagnosis. The modified definition of COD that we are finalizing will continue to exclude drugs from the definition of COD that are provided as part of, or as incident to and in the same setting, as defined in section 1927(k)(3)(A) through (H) of the Act, for which payment for the drug is bundled and not distinguishable from other costs associated with that service. In addition, given that under a bundled payment, the units of a drug that were provided during the service are not identified on the bill, the State would not know how many units to bill for rebates. We modified the proposed regulatory definition in this final rule such that in order for the definition of direct reimbursement to be met, the number of units administered to the patient must be identified on the invoice for the inclusive payment and

reflected in a payment methodology in the State plan.

Comment: Several commenters noted that some States are reimbursing the hospital for their acquisition cost of certain new and innovative therapies separately from their inpatient services associated with administering the drug. They believe this would qualify as direct reimbursement, and result in States adequately reimbursing providers/hospitals and encouraging patient access. One commenter suggested that accounting for the drug cost separately in the reimbursement calculation is a win-win situation.

Response: We agree that payment for drugs provided in this manner consistent with the State plan constitutes a direct reimbursement and the drug meet the definition of a covered outpatient drug.

Comment: A few commenters stated that the proposed definition could make drugs reimbursed under a DRG reimbursement methodology or other bundled payment subject to rebates when they historically were not. These commenters supported this result and noted that these drugs are currently carved out of DRGs to collect rebates. They noted that this clarification would ensure States have the authority to collect rebates regardless of the State's COD reimbursement methodology. These commenters stated this may be particularly important for new high-cost cell and gene therapies which are typically administered in medical facilities.

Response: We agree the proposed definition could have been interpreted to make drugs reimbursed under a DRG reimbursement methodology or similar bundled payment methodology subject to rebates regardless of the State's COD reimbursement methodology. As indicated in response to previous comments, we did not intend for the modification of the definition of COD to change current policy, but our review of comments alerted us to the fact that the proposed definition could be open to multiple interpretations. Based on such comments, we have modified the definition in this final rule to clarify that direct reimbursement does not occur unless the reimbursement for the drug is based on a reimbursement methodology that is included in the applicable section of the State plan, and that the inclusive payment includes an amount directly attributable to the drug. Thus, a drug that is reimbursed as part of a bundled payment under a DRG or similar bundled payment methodology is not subject to rebates. However, if that drug is carved out of the bundled payment and reimbursed directly, then

the drug is subject to rebates when applicable.

Comment: One commenter stated CMS should encourage State Medicaid programs to implement reimbursement methodologies for gene therapies that adequately cover both the direct gene therapy costs and the patient care costs for services incident to that therapy.

Response: We note that reimbursement for gene therapies, as with all CODs, are subject to section 1902(a)(30)(A) of the Act's requirements ensuring that States' "payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."

Comment: One commenter stated that separate payment creates greater equity in reimbursement rates across settings of care, such as inpatient hospital versus outpatient hospital reimbursement.

Response: Our definition of COD is not designed to address site of service concerns such as those raised by this commenter. Rather, it addresses when drugs are considered CODs, and thus the States can collect rebates, within various reimbursement methodologies.

Comment: One commenter stated that allowing States to seek rebates on inpatient-administered drugs merely by identifying the drug on the claim form and without some form of separate payment, would enable States to seek rebates on drugs without establishing the separate payment policies that make hospitals whole and help ensure patient access.

Response: We agree that this is a potential outcome of defining direct reimbursement without requiring a separate reimbursement policy to account for the cost of the drug via the applicable State plan, and that was not our intent. Our modified definition of direct reimbursement as finalized addresses this potential issue by requiring that the methodology for determining the reimbursement for a COD as part of a bundled payment be set forth in the State plan.

Comment: A few commenters stated CMS does not explain what the "itemized cost" represents and how it is to be determined and claimed it could essentially be a "fictional amount."

Response: This term is being revised in this final rule to "the charge for the drug". Providers should rely on the State's billing instructions to determine what to report to allow for appropriate reimbursement.

Comment: A commenter questioned whether the bundled service must be one in which the drug is always used.

Response: As noted in previous responses to comments, the definition, as finalized in this rule, makes it clear that in order for the drug to satisfy the COD definition, the drug used must be identified, the charge for the drug must be itemized on the claim form, and the payment must be consistent with the reimbursement methodology for CODs in an approved State plan. These requirements may apply to drugs that are always used in the bundled services and to drugs for which this is not the case.

Comment: Commenters stated that simple "itemization" on a claim form is not equivalent to "direct reimbursement."

Response: We agree, and therefore modified the definition in the rule to more clearly state that direct reimbursement includes a distinct methodology reflected in the State plan that accounts for the reimbursement of the drug and is used to determine the inclusive payment.

Comment: A few commenters stated that States would respond to this modified definition of COD by requiring providers to include NDCs and ingredient costs on all PAD claims in the future. One commenter recommended that CMS consider the impact that its new proposed definition has on providers' administrative burdens by requiring collection of NDCs and ingredient cost information, suggesting that including such information on Medicaid claims forms is both time-consuming and labor-intensive.

Response: We appreciate the comments regarding the potential burden to providers. Under their State plans, States have the discretion to choose which reimbursement methodology to use for health care services and what drugs, if any, they will carve out from that methodology and directly reimburse for them. As of January 1, 2007, CMS regulations at § 447.520 have obligated States to require that providers submit NDCs for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary. Additionally, we note that in section II. L. of this rule, States are required to provide for the collection of NDCs for all physician-administered single source drugs and multiple source drugs.

Comment: Some commenters stated that if a drug satisfies the definition of COD, all requirements of section 1927 of the Act apply (for example, all drugs of the manufacturer must be covered

regardless of hospital formularies, and reimbursement methodology must be described in the State plan).

Commenters acknowledged that States could impose prior authorization requirements and that coverage decisions should rest with the State and not the hospital. One commenter suggested that States not be allowed to skirt the coverage requirements of section 1927 of the Act by allowing hospitals to exclude from their inpatient formulary drugs of a manufacturer that has signed a NDRA. A few commenters expressed their concerns with their view that the proposed rule did not address how a bundled drug would be covered in the inpatient setting where restrictive formularies may apply.

Response: If a drug typically administered in the inpatient setting qualifies as a COD, then we agree, notwithstanding exclusions, that section 1927 of the Act applies to that drug. Our revised definition of COD does not change the State's ability to decide the reimbursement methodology for drugs so long as it is approved in their State plan.

Comment: One commenter stated that all reimbursement limitations that apply to CODs would need to apply to these bundled hospital inpatient drugs, specifically the Federal upper limit requirements found in §§ 447.512 and 447.514. The commenter noted that this issue is not addressed in the proposed rule by the lack of new language at § 447.516 "Upper limits on drugs furnished as part of service".

Response: We did not intend for the modification to the definition of COD to change current policy, including Federal upper limit regulations, but our review of comments alerted us to the fact that the proposed definition as originally written could be open to multiple interpretations. A "bundled" hospital inpatient drug that the commenter mentions, for which direct reimbursement is not made, does not qualify as a COD. Generally, the Federal upper limit requirements only apply to multiple source drugs dispensed by a retail community pharmacy. The regulatory language in § 447.516 applies Federal upper limits to payment for prescribed drugs furnished as part of a service when provided as part of a skilled nursing facility service, intermediate care facility service and under prepaid capitation arrangement. This change to the COD definition does not make any changes to the regulatory language in § 447.516.

After considering the issues raised by the commenters, we have decided to finalize this provision with modifications to our proposed

definition. In order for a payment to be considered direct reimbursement for a drug, the claim must include the charge for the drug, the number of units utilized, and the payment made to the provider must include an amount directly attributable to the drug and is based on a CMS approved reimbursement methodology.

b. Proposal To Define Drug Product Information (§ 447.502)

Section 1927(b)(3)(A) of the Act describes the manufacturer drug product and pricing information that is required to be reported to the agency. Section 6(a)(1)(A)(iv) of MSIAA amended section 1927(b)(3) of the Act by adding section (b)(3)(A)(v), under which a manufacturer must report drug product information that the Secretary shall require for each of the manufacturer's CODs no later than 30 days after the last day of each month of a rebate period. To support the implementation of this new statutory requirement to report drug product information, we proposed to define drug product information in regulation at § 447.502.

In the proposed rule, we noted that we currently require manufacturers to submit drug product information when the COD is entered into the Medicaid Drug Programs (MDP) system, but that there is no regulatory definition of drug product information. We, therefore, proposed to define "drug product information" in § 447.502 as information that includes, but is not limited to, NDC number, drug name, units per package size (UPPS), drug category (single source drug (S), innovator multiple source drug (I), and noninnovator multiple source drug (N)), unit type (for example, tablet, capsule, milliliter, each, etc.), drug type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension drug indicator, 5i indicator and route of administration, if applicable, FDA approval date and application number or OTC monograph citation if applicable, market date, COD status, and any other information deemed necessary by the agency to perform accurate URA calculations.

As discussed in the proposed rule, the drug category for an NDC should be single source drug or innovator multiple source drug for the entire history of the NDC if it was always produced, distributed, or marketed under an NDA, unless a narrow exception applies, or single source if marketed under a BLA. If a narrow exception has been granted by CMS, the drug category for that NDC should historically be reported as single source drug or innovator multiple

source drug, and can be changed to noninnovator multiple source drug, effective April 1, 2016. We noted that we use the FDA "applications.txt" file to verify the type of application associated with an application number and that the file may be accessed using the link to the Drugs@FDA download file found on the FDA website at <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files>.

We also noted in the proposed rule that the only situation in which a drug that is produced or marketed under an NDA may be reported as a noninnovator multiple source drug is if a narrow exception was granted by CMS in accordance with the process established in the 2016 COD final rule. See 81 FR 5191. Definitions for these drug categories can be found at section 1927(k)(7) of the Act and at § 447.502.

We indicated that manufacturers should evaluate all of their NDCs for compliance with drug product information reporting, and if they determine corrections are required, they should contact CMS for assistance. We also referenced Manufacturer Release No. 113, in which we addressed a manufacturer's responsibility to ensure that all of their CODs are correctly classified and reported in the Drug Data Reporting system (DDR) (currently known as the MDP system) for the history of the NDC, including such NDCs that may no longer be active (<https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf>). We also noted that as part of a manufacturer's evaluation of their NDCs for compliance with accurate drug product information reporting, they should ensure that each NDC is reported with an accurate market date.

In the proposed rule, we proposed to add a definition for "market date" for the purposes of the MDRP. Please see proposed § 447.502 for that proposed definition and elsewhere in this preamble for an explanation of how market date is used to determine the quarter that establishes each drug's base date AMP.

For most drug product information changes, we noted we would make the requested changes on behalf of the manufacturer in the CMS system, and those changes would subsequently be available for manufacturer certification. However, we noted that in some situations where monthly or quarterly pricing data must be updated as a result of the drug product information change, if necessary, we would notify the manufacturer that certain pricing data fields have been "unlocked" in the CMS system to allow the manufacturer to enter or correct required pricing

information if applicable. Additionally, we noted that regardless of whether we make a data change on behalf of a manufacturer or whether the manufacturer enters required data directly in the MDP system, manufacturers would be required to certify the information in accordance with § 447.510. Thus, we indicated that if we make a data change at the request of a manufacturer, the manufacturer is not relieved of its responsibility to ensure the accuracy of such data.

We also stated that until certification is complete, the changes in the CMS system are not considered final and would not be used in any quarterly rebate calculations or transmitted to the States as part of the quarterly rebate files; however, the manufacturer is still responsible for correct URA calculations and rebate payments. If drug product information changes remain uncertified, the previously certified values would remain in effect; therefore, corrections made in the CMS system that remain uncertified would result in the drug continuing to be considered misclassified or misreported. We noted that we would consider this to be late reporting of product data for which a manufacturer's rebate agreement may be suspended from the MDRP under section 1927(b)(3)(C)(i) of the Act and eventually terminated as authorized under section 1927(b)(4)(B) of the Act.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments supporting our proposed definition of drug product information. Commenters indicated that the proposed definition removes ambiguity and closes potential loopholes.

Response: We appreciate the commenters' support for the proposed definition of drug product information.

Comment: A few commenters stated that the statute's scope is limited to drug product attributes found in the statute and the regulation, and that several data elements that we included in the definition are not found in statute or regulation.

Response: We disagree that drug product information must be limited to product attributes specifically mentioned in the statute. The statute provides direction for CMS to administer the MDRP, which includes how rebate amounts are calculated. Some data fields that are utilized in calculating the unit rebate amount are not specifically set forth in statute but are nonetheless required to perform the calculations that are detailed in the statute or to confirm the accuracy of

those calculations. For example, although “unit type” is not a data element mentioned in statute, it is an important data element that helps to identify what the reported AMP represents. If the unit type is reported incorrectly, it is possible that the AMP value may be misinterpreted. CMS has determined to set forth by regulation the data elements that must be reported as part of drug product information.

Comment: One commenter suggested CMS limit the items included in the definition of drug product information to those items related to drug category.

Response: We are not limiting the items included in the definition of drug product information to those items related to drug category because we do not believe that approach would be consistent with the statute. MSIAA inserted the words “and drug product” to the title of section (b)(3) of the Act, as well as other references to drug product information, when addressing the information required to be reported by manufacturers and the misclassification of drugs. Therefore, the definition must include not only elements that are related to drug category, but also other elements that are required to perform the calculations of the unit rebate amount and to be able to help confirm the accuracy of the calculations in accordance with the statute. CMS believes the elements chosen for inclusion in this definition are essential to ensure that unit rebate amount calculations are accurate, and that CMS has accurate data to be able to oversee the MDRP.

Comment: One commenter requested clarification on the inclusion of base date AMP as an element of drug product information and questioned if the current file format will be amended to include base date AMP.

Response: The current file format will not need to be amended for the reasons explained later in this section. In order to fully respond to this comment, we need to delineate between different base date AMP values. If a drug has a market date of September 30, 1990, because it was first available for sale on or before that date, then the base AMP for the drug is referred to as the OBRA '90 base date AMP. The OBRA '90 base date AMP value, as well as all of the different base date AMP values, are considered to be product data. A manufacturer reports the OBRA '90 base date AMP value into MDP as part of the product data when first reporting the drug to CMS. The OBRA '90 base date AMP value is a value on the product data file (Form CMS-367c), and no file format amendments are required.

In general, if a drug has a market date after September 30, 1990, which is the date it was first available for sale, the base date AMP values are derived from quarterly pricing information that is reported by the manufacturer for the base AMP quarter. For each base date AMP value other than the OBRA '90 base date AMP value, the MDP system automatically populates the base date AMP value in the product data using the quarterly pricing information submitted by the manufacturer as pricing data for the base AMP quarter. Although these other base date AMP values are derived from quarterly pricing information for the base AMP quarter, the base date AMP values are not considered to be pricing data. Those base date AMP values other than the OBRA '90 base date AMP values are not reported directly into MDP as product data and do not appear in the product data file.

Comment: A few commenters stated that the changes that the Congress made to the statute were to address misclassifications, not drug pricing issues, and therefore any drug pricing references should be removed from definition of drug product information.

Response: The changes to the statute made by MSIAA are not solely to address drug category, but also to address incorrect reporting of additional drug product information. The items included in the definition of drug product information are all considered to be product information. As an example, although the base date AMP value is a pricing value, it is considered product information. It generally does not change once established and is tied to the drug throughout the history of that drug in the MDP system. Pricing information is reported monthly and quarterly and may change from one reporting period to the next.

Additionally, elements such as unit type or TEC code are not directly related to drug category, however they are included in the definition of drug product information.

Comment: A few commenters stated that the definition of drug product information must be prospective only and that CMS should clarify the effective dates of definition changes.

Response: The definition of drug product information becomes effective on the effective date of this final rule. With this definition of drug product information, we are not adding or changing any reporting requirements, we are only defining which reporting elements are included in the definition of drug product information.

Comment: A few commenters were concerned that the proposed rule would treat a clerical error that has no impact

on the MDRP the same as a misreported data element that has direct impact on URA calculations, such as base date AMP.

Response: The proposed definition of drug product information lists the data elements that are considered to be drug product information. The definition itself does not indicate how misreporting of any element of drug product information will be evaluated for potential penalties; misclassification of drug product information is addressed in the misclassification section of the rule. In that section, we state that we believe misclassification includes any incorrect drug product information reported by the manufacturer. Also in that section, we proposed several penalty options in accordance with the penalty options contained in section 1927(c)(4)(B) of the Act and note that CMS may utilize one or more of them in each situation. One of those options is for CMS to correct the misclassification on behalf of the manufacturer using drug product information provided by the manufacturer. As discussed in the misclassification section, the enforcement provisions in section 1927(c)(4)(B)(ii) provide options for CMS to take action when a manufacturer fails to correct a misclassification. CMS' current process within the MDP system requires the manufacturer to certify any change made in the MDP system. However, CMS may certify changes on behalf of the manufacturer and would do so in this specific situation. Outside of this specific situation, as discussed in the preamble of the proposed rule, any change made in the MDP system by CMS must be certified by the manufacturer before it becomes effective.

Comment: We received several comments regarding the “open-ended” definition of drug product information. Commenters were concerned that although we listed specific data that would be included in the definition, we also specified that the definition was not limited to those data elements. Specifically, commenters disagreed with the inclusion of “information that includes but is not limited to” and “and any other information deemed necessary by the Agency to perform accurate Unit Rebate Amount calculations.” Commenters stated that we lack the authority to leave the definition open-ended, that issuing “catch-all” phrases in definitions bypasses the notice and comment requirements, and that we must define terms with precision. Other commenters were concerned that the broad, open-ended provision in the

definition gives CMS a vehicle for arbitrary enforcement and leaves open the opportunity for inconsistent application year to year. One commenter stated that we should either strike the open-ended definition or delete “drug product information” from § 447.509(d)(1).

Response: While we disagree that we lack the authority to adopt provisions such as the definition proposed, we agree with the commenters that it would be appropriate to remove the “open-ended” provisions in the proposed definition of drug product information. We are additionally making slight edits to the construction of the proposed definition to make it clear to which elements the term “if applicable” applies. Therefore, drug product information will now be defined as National Drug Code (NDC), drug name, units per package size (UPPS), drug category (“S”, “I”, “N”), unit type (for example, TAB, CAP, ML, EA), drug type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension drug indicator, 5i indicator, 5i route of administration (if applicable), FDA approval date, FDA-approved application number or OTC monograph citation (if applicable), market date, and COD status.

Comment: A few commenters stated that the language proposes that manufacturers would have to report each element of drug product information repeatedly and that would be burdensome or unnecessary.

Response: Section 1927(b)(3)(A)(v) of the Act states that manufacturers must report, not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require for each of the manufacturer’s covered outpatient drugs. Currently, we require that drug product information be reported not later than 30 days after the date of entering into a rebate agreement, or, for newly introduced drugs, not later than 30 days after the last day of the month during which the new drug is introduced. Such drug product information is not required to be reported on a monthly or quarterly basis at this time, and we therefore disagree with commenters’ concerns that the definition requires unnecessary, repetitive, or overly burdensome reporting.

Based on the comments received, we are finalizing the definition as proposed with the previously described sentence structure changes and the following additional changes:

- Deleting “. . . includes but is not limited to . . .” and replacing it with “means”

- Deleting “. . . COD status, and any other information deemed necessary by the agency to perform accurate unit rebate amount (URA) calculations.” and replacing it with “and COD status.”

c. Proposal To Define Internal Investigation for Purposes of Pricing Metric Revisions (§§ 447.502 and 447.510)

In the proposed rule, we included a provision that would define internal investigation related to manufacturer reporting of quarterly pricing metrics. As background, we noted in the preamble to the proposed rule, in accordance with section 1927(b)(3) of the Act, § 447.510 of the implementing regulations, and the terms of the NDRA, manufacturers are required to report certain pricing and drug product information to CMS on a timely basis for the purposes of the MDRP, or else they could incur penalties or be subject to other compliance and enforcement measures. We noted that in an effort to improve the administration and efficiency of the MDRP and assist States and manufacturers that would otherwise be required to retain drug utilization pricing data records indefinitely, we established the 12-quarter time period for reporting revisions to AMP or best price information in final rule (Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program) on August 29, 2003. However, we have continued to receive requests outside of the 12-quarter time period from manufacturers to revise pricing data. We stated that these types of manufacturer requests, which could span multiple years prior to the 12-quarter time period, could sometimes result in substantial recoupment of Medicaid rebates already paid to States and impede the economic and efficient operation of the Medicaid program.

We noted that in the 2016 COD final rule we offered exceptions to the 12-quarter time period (81 FR 5278, See § 447.510(b)(1)(i) through (vi)). Specifically, we discussed one exception at § 447.510(b)(1)(v) (which provides an exception to the 12-quarter time period price reporting rule if the change requested by the manufacturer is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or Department of Justice (DOJ) investigation) pertaining to adjustments pursuant to an internal investigation. We explained that our policy has been that internal investigation is intended to mean a manufacturer’s internal investigation,

and that if a manufacturer discovers any discrepancy with its reported product and pricing data to the MDRP that is outside of the applicable timeframes, the manufacturer should determine if the change satisfies one of the enumerated exceptions (81 FR 5280). However, we acknowledged that we have not further defined or given any greater explanation for the applicability of the exception to the 12-quarter time period rule up to that point, particularly in instances when manufacturers perform an internal investigation of the drug price information (AMP and best price) reported and certified in MDP by another manufacturer. Additionally, we noted that, given the absence of a definition of internal investigation or specificity as to when this exception applies, some manufacturers have broadly interpreted the internal investigation exception to the 12-quarter time period rule. Consequently, in the proposed rule, we proposed a definition to provide greater clarity in this area. Our requirement does not override or otherwise diminish a manufacturer’s obligation to make sure that it has paid the statutorily required rebate amount. The discussion herein only applies to the paragraph of § 447.510(b)(1)(v) “internal investigation” and does not obviate or negate any requirement resulting from a CMS or court order, or an OIG or DOJ investigation.

In cases when a manufacturer requests an exception to the 12-quarter time period rule due to an internal investigation, we proposed to specify that the manufacturer must make a finding that indicates a violation of statute or regulation before we consider such a request. For example, a request by a manufacturer to restate or revise previously reported and certified pricing data outside of the 12-quarter time period based upon a mere disagreement with a prior manufacturer’s government pricing calculations and assumptions, would not be considered a valid reason to revise a prior manufacturer’s pricing outside of the 12-quarter time period. In this example, the manufacturer must make findings that include actual data from the prior manufacturer as evidence that the prior manufacturer violated statute or regulation.

We noted in the preamble to the proposed rule that manufacturers should not use the internal investigation exception to allow for application of a different methodology or reasonable assumption to determine AMP and best price to its favor when the methodology originally applied was consistent with statute and regulation, and drug product and pricing information was properly

reported and certified by the manufacturer at the time. Therefore, to ensure clarity on when the internal investigation exception may be appropriately applied, we proposed to define internal investigation at § 447.502 to mean a manufacturer's investigation of its AMP, best price, customary prompt pay discounts, or nominal prices that have been previously certified in MDRP that results in a finding made by the manufacturer of fraud, abuse or violation of law or regulation. We further indicated that a manufacturer must make data available to CMS to support its finding. We also proposed to amend § 447.510(b)(1)(v) to reference the definition of internal investigation at § 447.502.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the proposed definition of internal investigation, with some stating that this definition will lead manufacturers to avoid internal audits and fail to identify violations of fraud, abuse, or violations of law or regulation, such that it would reduce the accuracy and reliability of price reporting metrics. The commenters encouraged CMS to develop a proposal that maintains the viability of the internal investigation exception to the 12-quarter time period rule, instead of foreclosing price revision requests following an internal investigation.

Specifically, commenters indicated that manufacturers would have to admit legal fault in order to request a restatement outside the 12-quarter time period, which would have a chilling effect on appropriate restatements when there is no legal fault. For example, commenters indicated that manufacturers that are risk averse, or maintain a more conservative approach to price reporting than the previous owner, would likely not pursue price revision requests because of admission of fault. The commenters further indicated that there are many reasons why a manufacturer's reported AMP and best price may require correction, including resolution of price disputes for certain providers/customers that eventually impact best price and/or AMP or discovery of good-faith mathematical errors. They stated that CMS should withdraw its proposal of the definition of internal investigation and recognize manufacturer requests outside the 12-quarter time period for what they are: good faith attempts to comply with complex and

consequential government reporting obligations.

Response: CMS believes that most manufacturers are making good faith attempts to comply with MDRP price reporting rules. CMS also maintains that manufacturers have sufficient time to address revisions in MDP to the manufacturer's AMP, best price, customary prompt pay discounts, or nominal prices within the 12-quarter time period (3-year time period) in accordance with the timeframe set in § 447.510. Through notice and comment rulemaking, CMS published the final rule (CMS-2175-FC) that set forth the 12-quarter (3-year) time period on August 29, 2003. In the 2003 final rule, CMS reiterated concerns expressed by States regarding pricing changes and recalculations that were occurring under the MDRP back to 1991, and the significant burden on States and manufacturers to maintain pricing data and supporting documentation for such an extended time period. Based on these considerations, a time limit was adopted (68 FR 51913). As there were no comments received regarding extending this period beyond 12-quarters in response to the 2003 proposed rule, CMS adopted the 12-quarter time period and communicated that we would not choose a longer period than 3 years because it would not sufficiently alleviate States' fiscal vulnerability with regard to retroactive pricing changes (68 FR 51916).

While we have enacted exceptions to allow for restatements in certain circumstances beyond the 12-quarter time period, we continue to believe that we should minimize requests to restate outside of that time period to improve the administration and efficiency of the MDRP and to assist States and manufacturers that would otherwise be required to retain drug utilization pricing data records indefinitely (88 FR 34253). As a result, we are finalizing the definition of internal investigation, but we are amending the definition to add the term "possible" so that such restatements would not be construed as an admission of legal fault. Therefore, as finalized, we will define internal investigation at § 447.502 to mean: a manufacturer's investigation of its AMP, best price, customary prompt pay discounts, or nominal prices that have been previously certified in the MDRP that results in a finding made by the manufacturer of possible fraud, abuse, or violation of law or regulation. A manufacturer must make data available to CMS to support its finding. CMS notes that neither the general 12-quarter time period for restatements nor the exceptions allowing for restatements in

certain circumstances beyond the 12-quarter time period, including pursuant to an internal investigation, alleviate the manufacturer of its obligation to accurately report product and pricing information for covered outpatient drugs to CMS consistent with section 1927 of the Act and applicable regulations and guidance.

Comment: A commenter indicated that a manufacturer may conclude after an internal investigation that it should change a unit type for a drug (for example, the unit type of a vial of lyophilized powder for reconstitution and injection from gram to each) based on CMS guidance. The commenter also indicated that although the use of the initial unit type is not a violation of law or regulation, let alone fraud or abuse, restatement beyond the 3-year window would be prohibited, and the prospective use of the preferable unit type would be precluded by the inability to correct the base date AMP. The commenter provided as another example a manufacturer that, as a result of an internal investigation, changes a reasonable assumption about a customer or its class of trade. The commenter noted that an internal investigation may uncover new information that a group purchasing organization (GPO) passes through administrative fees to its members, or that a pharmacy dispenses greater than 50 percent of its prescriptions through the mail, which the commenter indicated could lead to a different treatment of the customer in the AMP and best price calculations.

Response: Existing regulation at 447.510(b)(1)(v) provides that if "[t]he change is to address specific rebate adjustments to States by manufacturers, as required by CMS . . ." and a manufacturer requests a change to a drug's unit type in our system because CMS has directed the manufacturer to make the change, that reason may be considered by CMS as an exception to the 12-quarter time period rule. Revisions to a manufacturer's determination of AMP and best price because a manufacturer uncovers new information about the calculation it made 12 quarters in the past may meet the exception only if the change is to address rebate adjustments to States as directed under 447.510(b)(1)(v). That is, the change is required by CMS or court order, or under an internal investigation (as defined at 447.502) or an OIG or DOJ investigation.

Comment: Several commenters noted that they are concerned with CMS' assertion in the proposed rule that a manufacturer purchasing another manufacturer or another manufacturer's products, are not valid reasons to restate

pricing outside of the 12-quarter limit. A commenter stated that revisions made outside of the 12-quarter time period conflict with a basic operating premise of the MDRP, as codified in the NDRA. That is, acknowledging the complexity of the Medicaid rebate statute and price reporting requirements, the commenter stated that CMS has long encouraged manufacturers to make “reasonable assumptions” in calculating price reporting metrics. As a result, the commenter noted that a manufacturer may revise the previously reported pricing data of a prior manufacturer using a different, reasonable methodology to align a newly acquired product with the reasonable assumptions and price reporting practices of existing company products.

Commenters also indicated that the proposed definition would prevent a manufacturer from requesting to restate pricing metrics calculated using the manufacturer’s preferred compliant method upon acquiring a new COD where the pricing metrics for the COD were initially reported with a different compliant method. They stated that this policy would discourage merging entities from harmonizing their reporting methods and could require a manufacturer to employ various methods of calculating pricing metrics to various different CODs, increasing the administrative burdens of complying with its reporting obligations and increasing the risk of reporting inaccuracies by introducing the potential for misapplication of the wrong calculation method for a given COD.

Response: CMS reiterates that we will not accept a change in pricing outside the 12-quarter time period because of a change in a manufacturer’s reasonable assumptions or ownership. The manufacturer may prospectively, or within the 12-quarter time period, revise reasonable assumptions associated with the drug pricing, including correcting any customer or class of trade transactions associated with the revised reasonable assumptions. Manufacturers may also harmonize their preferred compliant methodology for pricing within the 12-quarter time period. Permitting manufacturers to revise prices retroactively that were previously verified by another manufacturer and in perpetuity because of changes to a transfer of ownership would be contrary to the established 12-quarter time period CMS adopted in rulemaking in 2003 under CMS–2175–FC. As previously noted, at that time, CMS decided not to extend the 12-quarter time period and communicated that we would not choose a longer recordkeeping than 3

years because it would not sufficiently alleviate States’ fiscal vulnerability with regard to retroactive pricing changes (68 FR 51916). Therefore, while we have established exceptions to the 12-quarter time period rule at § 447.510(b), we believe we should minimize granting requests outside of the 12-quarter time period, including restatements of pricing reported for a product previously owned, reported, and certified by another manufacturer.

Also, as noted in a prior response to comments, CMS seeks to minimize requests to restate drug pricing information outside of the 3-year timeframe to improve the administration and efficiency of the MDRP and assist States and manufacturers that would otherwise be required to retain drug utilization pricing data records indefinitely (88 FR 34253). In this regard, we continue to believe the 12-quarter time period with the existing exceptions, as clarified in this final rule, allows manufacturers to revise pricing without disrupting the administration and efficiency of the MDRP. We note that if a manufacturer is concerned with liability associated with the prices or pricing metrics used by the selling manufacturer, CMS believes that such concerns regarding legal liability because of the incorrect reported price information should be addressed as part of contract negotiations between the selling and buying manufacturer.

Comment: One commenter supported CMS’ request for data to support compliance with laws and regulations in 12-quarter time period rule exception requests. The commenter agreed that it sets a clearer and stricter standard for the exception of the 12-quarter time period by excluding subsequent internal reviews to revise in the manufacturer’s favor pricing data that was compliant with laws and regulations.

Response: We agree with the commenter that the use of data to support revisions to prices outside of the 3-year timeframe to reinforce a manufacturer’s finding of potential non-compliance with laws and regulations establishes a clear standard for when an exception may apply. We believe the definition of internal investigation, as finalized in this rule, will address this concern.

Comment: A commenter indicated that the inability to restate a base date AMP to harmonize different calculation methods could distort the Medicaid additional rebate calculation. Such rebates are calculated by reference to the difference between a COD’s current AMP and its baseline AMP. The commenter stated that if a manufacturer

is prevented from restating baseline AMP under its current AMP calculation method, then the additional rebate calculations for every future period will be distorted by the methodology difference.

Response: Manufacturers can restate base date AMP within 3 years of the initial price reported consistent with § 447.510(b). Furthermore, when CMS issues final regulations to reflect revisions made to the statute’s calculation of AMP, CMS allows manufacturers to restate their base date AMP in accordance with those regulatory and statutory changes so that the baseline AMP is consistent with the reported AMP. For example, in the 2016 COD final rule, CMS permitted manufacturers to recalculate their base date AMP in accordance with the revisions made to the determination of AMP under the Affordable Care Act (see 81 FR 5281). In accordance with the § 447.502 definition of internal investigation, as finalized in this rule, CMS will not permit a manufacturer to revise the base date AMP outside of the 3-year timeframe unless the internal investigation results in a finding made by the manufacturer of possible fraud, abuse, or violation of law or regulation.

Comment: Several commenters pointed out that rebates under the Medicare Part D Drug Inflation Rebate Program for Part D rebateable drugs are calculated by reference to the amount by which the drug’s “annual manufacturer price” (AnMP) exceeds the “inflation-adjusted rebate amount.” AnMP is calculated by using, in part, the AMP of a drug over 4 calendar quarters. The commenters indicated that any inflation rebate calculated for Medicare Part D purposes could also be distorted by CMS’ proposal. They stated that if manufacturers are prevented from restating AMP under this proposal in MDRP rulemaking, then future Part D rebate calculations will be based on the same distorted comparison as the Medicaid rebates. They also noted that as AnMP and the benchmark period manufacturer price are calculated by using multiple quarterly AMPs, any adjustments to CMS’ proposed redefinition intended to avoid these distortions should allow manufacturers to restate AMP for all quarters relevant to these calculations for the particular drug.

Response: As noted in the response to the previous comment, manufacturers can restate base date AMP within 3 years of the initial price reported consistent with § 447.510(b), and CMS will allow manufacturers to revise base date AMP to reflect revisions made to the statute’s calculation of AMP.

However, in accordance with the § 447.502 definition of internal investigation as finalized in this rule, CMS will not permit a manufacturer to revise the base date AMP outside of the 3-year timeframe unless the manufacturer's investigation results in findings of possible fraud, abuse, or violation of law or regulation. As previously stated and in the proposed rule, the definition will clarify for manufacturers that they should not use the internal investigation exception to allow for the application of a different methodology or reasonable assumption to determine AMP and best price to its favor when the methodology originally applied was consistent with statute and regulation, and drug product and pricing information was properly reported and certified by the manufacturer previously. CMS has published revised guidance with respect to the operation of the Medicare Part D Drug Inflation Rebate Program, *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1860D-14B of the Social Security Act*,⁸ and is engaged in rulemaking for this program.⁹ CMS refers commenters to Medicare Part D Drug Inflation Rebate Program materials for information on how the Medicare Part D Drug Inflation Rebate Program will use AMP data for the purposes of calculating inflation rebates.

Comment: Several commenters believe that the proposed rule would discourage manufacturers from taking the required measures of correcting the calculations beyond the 12-quarter time period, which could result in calculations that are inconsistent with the manufacturer's methodology and may result in favor of the State. The commenters suggested that CMS allow manufacturers to submit policy changes prior to the 12-quarter time period and seek approval from CMS with documentation and the reason for the policy change, but not necessarily details pertaining to pricing impact either in States or manufacturer's favor. The commenters indicated that, if CMS does not approve the manufacturer's policy changes prior to the 12-quarter time period, then the manufacturer should not proceed with restating the price. The commenter also suggested that manufacturers be allowed to get approval from CMS to recalculate prices

when the manufacturer has identified new or changed information in the underlying data which caused the earlier calculation to be incorrect.

Response: We believe the commenter is requesting that CMS approve a manufacturer's pricing methodology or change in information prior to the manufacturer submitting a restatement beyond the 12-quarter time period and not before the 12-quarter time period. Current CMS policy allows the manufacturer to change its pricing information prior to the 12-quarter time period without requesting CMS approval. CMS has a long-held policy that a manufacturer that needs to make future recalculations regarding AMP or best price methodology may do so without prior review and approval by CMS and that manufacturers must report to CMS these revisions to AMP and or best price for a period not to exceed 12 quarters from the quarter which the data were due.¹⁰ This final rule does not impact this CMS policy. However, if the manufacturer provides findings to CMS that the manufacturer's pricing methodology may result in possible fraud, abuse, or violation of law or regulation, CMS may consider permitting the manufacturer to restate its pricing based on the revised methodology outside of the 12-quarter time period.

Therefore, as we noted in the response to the previous comment, we will finalize the definition of internal investigation but amend the definition to add the term "possible" so that a manufacturer's restatements would not be construed as an admission of legal fault. Instead, we will define internal investigation at § 447.502 to mean: a manufacturer's investigation of its AMP, best price, customary prompt pay discounts, or nominal prices that have been previously certified in the MDRP that results in a finding made by the manufacturer of possible fraud, abuse, or violation of law or regulation. A manufacturer must make data available to CMS to support its finding.

d. Proposal To Revise the Definition of Manufacturer for NDRA Compliance (§ 447.502)

We proposed to further refine the definition of manufacturer at § 447.502 to codify the requirements under section 1927(a)(1) of the Act, which specifies that a manufacturer has to have entered into and have in effect a rebate agreement with the Secretary in order

for payment to be available for their CODs under Medicaid. We also proposed to codify in regulation that all entities (with their applicable labeler codes) that are associated or affiliated with a manufacturer must have a rebate agreement in effect in order for the manufacturer to satisfy the statutory requirement that the manufacturer have a rebate agreement in effect with the Secretary.

CMS received a number of thoughtful comments on this topic, and we determined not to finalize the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

e. Proposal To Define Market Date (§ 447.502)

In the proposed rule, we included a provision that would establish a definition for market date in regulation. This proposed definition would: (1) modify one aspect of previous agency guidance regarding the market date for a drug by requiring in regulation that the market date reflect the date of first sale of the drug, rather than the date the drug was first available for sale, by any manufacturer; and, (2) codify CMS' historical policy that the market date does not change if a drug is purchased or otherwise acquired from another manufacturer.

Prior instructions and guidance to assist manufacturers in determining the market date for a drug to report to MDP specified that the market date was the date the drug was first available for sale by any manufacturer. This prior guidance is available in various sources, including program notices, the MDP User Guide located within MDP, user manuals previously available in the older Drug Data Reporting for Medicaid (DDR) system, and in data definitions in CMS form 367c.

As background in the preamble to the proposed rule, we noted that section 1927 of the Act governs the MDRP and payment for CODs, which are defined in section 1927(k)(2) of the Act. Pursuant to section 1927(b)(1)(A) of the Act, manufacturers that participate in the MDRP are required to pay rebates for CODs that are dispensed and paid for under the State Medicaid plan. Additionally, section 1927 of the Act provides specific requirements for program implementation, including requirements for rebate agreements, submission of drug pricing and product information, confidentiality, the formulas for calculating rebate payments, and many others related to State and manufacturer obligations under the program. The rebates owed by

⁸ <https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf>.

⁹ <https://www.federalregister.gov/documents/2024/07/31/2024-14828/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other>.

¹⁰ Manufacturer Release #80: (<https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-080.pdf>).

manufacturers are calculated based on statutory formulas described in section 1927(c) of the Act and consist of a basic rebate and, in some cases, an additional rebate that is applicable when an increase in the AMP, with respect to each dosage form and strength of a drug, exceeds the rate of inflation. This additional rebate formula is set forth in sections 1927(c)(2) and 1927(c)(3)(C) of the Act and codified in regulation at § 447.509(a)(2) and (7).¹¹

We also noted in the proposed rule that the additional rebate calculation requires a determination of the AMP for the dosage form and strength of the drug for the current rebate quarter, and a comparison of that AMP to the AMP for the dosage form and strength of that drug for a certain calendar quarter, generally referenced as the base date AMP quarter.¹² For S or I drugs, the base date AMP quarter is the third quarter of 1990 for drugs that were first marketed prior to fourth quarter of 1990, or the first full calendar quarter after the day on which the drug was first marketed for drugs that were first marketed on or after October 1, 1990.¹³ (See sections 1927(c)(2)(A) and 1927(c)(2)(B) of the Act.) For other drugs (including N drugs and other drugs reported as N), we noted that the base date AMP quarter is the third quarter of 2014 for drugs that were first marketed prior to April 1, 2013, or the fifth full calendar quarter after the day on which the drug was first marketed for drugs that were first marketed on or after April 1, 2013. (See section 1927(c)(3)(C) of the Act.) To determine the applicable base date AMP and, ultimately, to calculate the additional rebate for a quarter, we noted

that a critical data point is the day on which the drug was first marketed. We refer to this date as a COD's market date. Manufacturers are required to report to CMS the market date of each dosage form and strength of a COD for all of its CODs.

We also noted that section 1927(c)(2)(A)(ii)(II) of the Act expressly provides that the base date AMP quarter, with respect to a dosage form and strength of a drug, is established without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer. As such, we noted that the market date of a drug is the date that the drug was first marketed, regardless of the entity that marketed the drug. Consistent with the statute, we noted that the market date of a drug is not and cannot be based on the first date upon which a subsequent manufacturer first markets the drug, but rather the earliest date on which the drug was first marketed, by any manufacturer.

We also stated that a new market date cannot be established for a drug that is marketed under the same FDA-approved NDA number, ANDA number, or BLA license unless the drug is a new dosage form or strength because the statute requires an additional rebate amount based on the market date for each dosage form and strength of a COD.¹⁴ Thus, if a drug is purchased or otherwise acquired from another manufacturer, we noted that the market date should not change, and should be the same as the market date of the drug first marketed under the FDA-approved application.

Because over the years, manufacturers have occasionally raised questions to CMS regarding the determination of a COD's market date, base date AMP quarter, and base date AMP under various fact-driven scenarios, we proposed to clarify the term market date as used in the MDRP and to resolve potential questions related to these issues. Specifically, to assist manufacturers in reporting a more accurately calculated AMP, for the purposes of determining the base date AMP quarter and the base date AMP, we proposed that the market date be based on the first sale of the drug by any manufacturer rather than the date the drug was first available for sale by any manufacturer. We indicated that linking the market date determination to the date of the first sale, rather than the date the drug was first available for sale,

would permit a manufacturer to establish and report a base date AMP based on actual sales data. As a result, the Unit Rebate Amount (URA) would also be calculated more accurately because actual sales would be available for reporting the AMP and calculating the URA.

In other words, under our proposal, for purposes of determining the base date AMP quarter and thus the base date AMP, the market date is based upon the earliest date on which the drug was first sold, by any manufacturer. As noted previously in this section, our proposal also would codify the existing requirement that the market date for a COD is determined with respect to "any manufacturer."

We also stated that we understand that defining market date, for purposes of determining a COD's base date AMP, based on the date the COD was first sold, may not completely eliminate a manufacturer's need to make reasonable assumptions because the first sale(s) may include only AMP ineligible sales. For example, if all the sales during the first quarter of a drug's availability are made to entities other than retail community pharmacies or wholesalers, and are not eligible for a 5i AMP calculation, then there may not be any AMP eligible sales to use for the calculation of AMP for that quarter. In such cases, a manufacturer may still need to use reasonable assumptions to report an AMP for that quarter.

We proposed that sold means that the drug has been transferred (including in transit) to a purchasing entity. We requested comments on this topic to determine what qualifies as "sold" for the purposes of determining the market date of a drug, as we have also experienced manufacturers interpreting the term "sold" differently across the industry.

We received public comments on the proposed definition of market date for the purposes of the MDRP. The following is a summary of the comments we received and our responses.

Comment: We received numerous comments expressing support for the proposed definition of market date and one comment that noted no concerns with the proposed definition.

Response: We appreciate the support of the proposed definition of market date.

Comment: We received a comment about how our proposed definition of market date might intersect with the way Medicare proposes to determine the market date for the purposes of certain provisions under the Inflation Reduction Act (IRA). Commenters suggested that applying the same

¹¹ Section 602 of the Bipartisan Budget Act (BBA) of 2015 amended section 1927(c)(3) of the Act, to require that manufacturers pay additional rebates when their covered outpatient drugs other than single source or innovator multiple source drugs' average manufacturer prices increase at a rate that exceeds the rate of inflation. In accordance with section 1927(c)(3) of the Act, as revised by section 602 of the BBA of 2015, manufacturers must calculate these additional rebates for these drugs beginning with the January 1, 2017 quarter (that is, first quarter of 2017).

¹² Base Date AMP is defined in the National Drug Rebate Agreement (NDRA) at I.(c) as follows: "Base Date AMP" will have the meaning set forth in sections 1927(c)(2)(A)(ii)(II) and 1927(c)(2)(B) of the Act. See also I.(l) definition of "marketed". Section VIII.(a) provides that the agreement is subject to any changes in the Medicaid statute or regulations that affect the rebate agreement. Thus, any changes to regulations are incorporated into rebate agreements without further action. See also Manufacturer Release 113—Misclassification of Drugs ([medicaid.gov](https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf)); <https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf>.

¹³ For a drug with a market date prior to October 1, 1990, the MDRP reporting system defaults to a market date of September 30, 1990. The system assigns a base date AMP quarter of fourth quarter of 1990 to such drugs as the statute defines (section 1927(c)(2)(A)(ii) of the Act).

¹⁴ The FDA approved application (for example the NDA itself) includes all FDA approved supplements to the application.

definition across CMS would provide consistency across the agency.

Response: CMS' interpretation of terms and the applicability of those terms for programs other than the MDRP are outside the scope of this final rule.

Comment: A few commenters suggested that we forgo setting forth a definition for market date and allow manufacturers to continue to make reasonable assumptions.

Response: We disagree that we should forgo finalizing a definition for market date, because we believe a regulatory definition will bring additional consistency to the MDRP and will assist manufacturers in identifying the accurate market date. However, to the extent the definition does not address a specific situation, manufacturers may still need to make reasonable assumptions. As an example, we discuss the potential need for reasonable assumptions further in our response to comments regarding the proposed definition of "sold" within the definition of market date.

Comment: One commenter questioned if the market date should be the same for all 11-digit NDCs within a 9-digit NDC family, even if an individual 11-digit NDC was introduced at a later time.

Response: The market date is the same for all 11-digit NDCs within a 9-digit NDC family. The 9-digit NDC identifies a drug, dosage form, and strength. The Package Size Intro Date (that is, the date of introduction of a particular package size, identified by the last segment of the 11-digit NDC), may or may not coincide with the market date of the drug, dosage form, and strength, and therefore the date of introduction of a package size is not a factor in determining the market date of the drug, dosage form, and strength for the purposes of determining AMP and URA. To reiterate, the market date for the 9-digit NDC applies to every 11-digit NDC in the family and is tied to the drug, dosage form, and strength marketed under an FDA-approved application; it is not tied to the Package Size Intro Date for a particular 11-digit NDC.

Comment: Several commenters discussed the effective date of the definition of market date. The commenters inquired whether the definition will be applied retroactively and suggested that retroactive application is not permitted and would be a burden on States and manufacturers.

Response: The definition of market date adopted under this final rule applies as of the effective date of this final rule. Specifically, if a manufacturer

previously reported a market date based on earlier program instructions that the market date was the earliest date the drug was *available for sale* by any manufacturer, they will not be required to change the market date to reflect the earliest date the drug was *sold* by any manufacturer. However, after the effective date of this final rule, manufacturers must use the earliest date the drug was sold as the market date for new drug products.

The finalized definition of market date will change how manufacturers determine what date to use to determine the value to report; that is, manufacturers must use the date of first sale of the drug, rather than the date first available for sale, as of the effective date of this final rule. The finalized definition does not make any changes to the already existing requirement that the market date is linked to the drug, dosage form, and strength that was first marketed under an FDA-approved application. Consistent with the statute and prior CMS guidance, the market date of a specific drug, dosage form, and strength does not change, even if the specific drug, dosage form, and strength might be subsequently marketed under a different NDC or by a different manufacturer. Specifically, prior instructions and guidance given by CMS to assist manufacturers in determining the accurate market date to report to MDP specifies that the market date is the date the drug was first available for sale under the FDA-approved application number by any labeler. This was first included in Manufacturer Release #69 (May 13, 2005). It is also included in CMS' NDRA Reference Guide, the MDP User Guide located within MDP, user manuals previously available in the older Drug Data Reporting for Medicaid (DDR) system, and in data definitions in CMS form 367c.

The finalized definition thus modifies one aspect of the previous guidance regarding market date by requiring that the relevant date be the date of first sale, while codifying CMS' historical policy that the market date does not change if a drug is purchased or otherwise acquired from another manufacturer. We reiterate that this finalized definition does not change the requirement given in previous instructions to report the market date as the earliest date the drug was available for sale by any manufacturer. For example, if a manufacturer that acquires a drug instead reports the date that they first made the NDC available for sale, then that manufacturer would be expected to correct or request that the market date be corrected in the MDP

system if they were not the earliest manufacturer to sell the drug. Manufacturer Release No. 113 (June 5, 2020), available at https://www.medicaid.gov/sites/default/files/2020-06/mfr-rel-113_0.pdf also addresses the historic policy. That release states:

"As manufacturers evaluate their NDCs for compliance, they should also ensure they are accurately reporting the drug's market date. As stated in section 4.15 of the Medicaid Drug Rebate Data Guide for Labelers June 2019 (available within [MDP]), the market date for S, I, and N drugs marketed under an FDA-approved application (for example, BLA, NDA, ANDA) is the earliest date the drug was first marketed under the application number by any labeler. If a drug was purchased or otherwise acquired from another labeler, the market date should equal the market date of the original product. However, if a market date entered into [MDP] falls on a date that is earlier than 9/30/1990, [MDP] automatically populates the market date field with a value of 9/30/1990 (because dates earlier than the start of the MDRP are not applicable).

In addition to being a required product data field under the MDRP, the market date is also used to determine the quarter that is used to establish each drug's Baseline Average Manufacturer Price (AMP). Because the Baseline AMP is used to calculate the additional rebate portion of the Unit Rebate Amount (URA) calculation, accurate market date reporting is imperative in order to ensure that correct Baseline AMP values are established. Prior to the implementation of the additional rebate for N drugs, manufacturers may have reported a market date that represented the date they began marketing the drug, rather than the earliest date that the drug was marketed under the application number by any labeler. If this is the case, a manufacturer must request a change from the incorrectly reported market date to the correct one to ensure that the correct Baseline AMP is accurately reflected in [MDP]. CMS addresses a manufacturer's responsibility with respect to correct reporting of baseline data for a drug that was purchased from another manufacturer in Manufacturer Release No. 90 and Manufacturer Release No. 101."

In order to request corrections to the market date, manufacturers should follow the instructions at <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-change-request/index.html>.

We also note that MSIAA added civil money penalties and provided enforcement authority if a manufacturer provides false information related to drug product information, which, as explained at section F of this final rule, includes the market date. Penalties that were added by MSIAA take effect as of the effective date of MSIAA. However, if correcting a misreported market date leads to changes in a drug's URA, manufacturers may be required to reconcile prior rebate payments with the States.

Comment: In response to a request for comments about how to determine what qualifies as sold for the purposes of determining the market date of a drug, we received several suggestions. Several commenters suggested CMS allow a manufacturer to use reasonable assumptions. Reasons provided for using reasonable assumptions included that manufacturers may identify their sale date based on commercial agreements, business practices, date of payment, date of invoice, and other determining factors. Other commenters suggested that a drug should be considered sold on the date it is transferred to a purchasing entity, or that it should be based on a customer invoice date.

Another commenter suggested that a sale only occurs if the purchaser is AMP-eligible.

Response: We agree that different manufacturers may record sale dates differently, based on their business practices. Therefore, although we proposed a definition for the term sold and requested comments regarding such a definition, we will not define sold as it applies to the definition of market date and will permit manufacturers to use reasonable assumptions as to the date a sale has occurred. However, this does not mean that a manufacturer should report a market date as the date they first sold the drug when another manufacturer first sold the drug, dosage form, and strength under the FDA-approved application number at an earlier date, as doing so would be inconsistent with our previous guidance and the requirements of section 1927 of the Act. Rather, the manufacturer needs to report the market date as the earliest date the drug was available for sale by any manufacturer.

We disagree that only sales to purchasers that are AMP-eligible should be considered when determining the date on which the drug was first sold. The first date of sale, and therefore the market date, does not depend on what entity is making the purchase.

After consideration of public comments on this provision, we are

finalizing the definition of market date as proposed. In the proposed rule we requested comments on what is meant by sold and what qualifies as being sold, and we incorporated the comments we received into our review of the definition of market date. We are not creating nor finalizing a definition of sold for the purposes of determining the market date of a drug.

f. Proposal To Modify the Definition of Noninnovator Multiple Source Drug (§ 447.502)

As discussed previously in the proposed rule, section 6(c) of MSIAA included a number of amendments to statutory definitions in section 1927 of the Act. Generally, those statutory amendments were discussed in the 2020 final rule (85 FR 87000, 87032) where the regulatory definitions of multiple source drug, innovator multiple source drug, and single source drug were amended consistent with MSIAA. However, although we made conforming changes to the regulatory definition of an I drug in the 2020 final rule, because MSIAA did not expressly amend the statutory definition of an N drug, we did not consider whether any changes to the regulatory definition of an N drug were necessary at that time.

In the proposed rule, after further evaluation, we proposed to amend the regulatory definition of an N drug to conform it to the regulatory definition of an I drug. We noted that when we established a regulatory definition of an N drug in the 2007 final rule, we did so to distinguish between multiple source drugs approved under an ANDA (generally referenced as N drugs) and multiple source drugs approved under an NDA (that is, I drugs). Both I drugs and N drugs are generally multiple source drugs. The main difference between the definitions is the authority under which the drug is marketed. Generally speaking, I drugs are marketed under an approved NDA, and N drugs are marketed under an approved ANDA or are unapproved.

We noted that section 1927(k)(7)(A)(iii) of the Act, which was not expressly amended or clarified by MSIAA, defines a noninnovator multiple source (N) drug as a multiple source drug that is not an I drug. As noted, MSIAA amended the statutory definition of an I drug by removing “was originally marketed” and adding “is marketed,” and we therefore made conforming changes to the regulatory definition of an I drug in the 2020 final rule. However, as noted in the proposed rule, when we modified the regulatory definition of an I drug to replace “was originally marketed” with “is

marketed,” we neglected to make a corresponding change to the definition of an N drug to maintain the clear distinction between an I drug, which is marketed under an NDA, and an N drug, which is not marketed under an NDA. We noted that paragraph (3) of the regulatory definition of an N drug, codified at § 447.502, continues to refer to a COD that entered the market before 1962 that was not originally marketed under an NDA.

To maintain and conform with the statute's clear distinction between an I drug and an N drug, we therefore proposed to amend paragraph (3) of the definition of an N drug at § 447.502 by removing “was not originally marketed” and inserting in place “is not marketed.” As amended, the regulatory definition of an N drug would, in relevant part, have the same structure as the statutory and regulatory definitions of an I drug and distinguish between a multiple source drug approved under an ANDA (that is, an N drug) and a multiple source drug approved under an NDA (that is, an I drug) based on the authority under which the drug is marketed, not how the drug was originally marketed.

Accordingly, we proposed to amend § 447.502 by revising paragraph (3) of the definition of an N drug to read, “A covered outpatient drug that entered the market before 1962 that is not marketed under an NDA.” We believe this to be a technical correction to the regulatory text.

We received public comments on this proposal. The following is a summary of the comments we received and our response.

Comment: One commenter stated that the group they represent did not report concerns with the proposed change in definition of noninnovator multiple source drug. Another commenter supported CMS' efforts to further clarify key program definitions, including the definition of noninnovator multiple source drug.

Response: We appreciate the support of the proposed definition of noninnovator multiple source drug.

After consideration of public comments, we are finalizing the definition of noninnovator multiple source drug as proposed.

g. Proposal To Define Vaccine for Purposes of the MDRP Only (§ 447.502)

In the proposed rule, we included a provision that would define vaccine for the purpose of operating the MDRP. As background, we noted that States that opt to cover prescribed drugs under section 1905(a)(12) of the Act in their State plan are required to do so

consistent with section 1927 of the Act, as set forth at section 1902(a)(54) of the Act.

Section 1927(k)(2)(B) of the Act specifically excludes vaccines from the definition of COD for purposes of the MDRP, and this provision is codified in paragraph (1)(iv) of the regulatory definition of COD at § 447.502. We noted in the proposed rule that section 1927 of the Act does not define vaccine, nor is there a relevant definition of vaccine in Title XI, XVIII, XIX, or XXI of the Act (applicable to Medicare, Medicaid, and CHIP) that speaks to the specific kinds of biological products that qualify as vaccines in terms of their actions in the human body and how and when they are used.¹⁵ Moreover, we noted that we are not aware that any authorizing statutes for any other Department of Health and Human Services agencies include such a statutory definition of the term vaccine. Therefore, we proposed a regulatory definition of vaccine for the purposes of the MDRP to specify which products are considered vaccines and thus excluded from the definition of COD.¹⁶

Specifically, we proposed to define vaccine at § 447.502 for the specific purposes of the MDRP, so that manufacturers understand which products are considered vaccines under the MDRP and are excluded from the definition of COD, and not subject to MDRP rebate liability. We proposed that the definition would be applicable only to the MDRP and would not be applicable to any other agencies or agency program implementation, including FDA and CDC. We stated that the definition will only be applicable to the HRSA 340B Program to the extent the definition defines what drug products are CODs but otherwise will have no applicability. We also stated that the definition of vaccine would not apply under any title XIX statutory

provisions other than section 1927(k)(2), or to separate CHIPs operating under § 457.70(a)(1) and (d), or for purposes of the VFC Program. However, we noted that the definition will apply to the MDRP for purposes of Medicaid expansion CHIPs, under § 457.70(c)(2). We stated that the proposed definition would also not apply with respect to any applicable Federal or State requirements to cover immunizations for Medicaid beneficiaries.

We proposed to define vaccine to mean a product that is administered prophylactically to induce active, antigen-specific immunity for the prevention of one or more specific infectious diseases and is included in a current or previous FDA published list of vaccines licensed for use in the United States. To meet the definition of a vaccine for the purposes of the MDRP, we proposed that a product must be administered prophylactically—that is, to prevent a disease and not to treat a disease—because we do not interpret the statutory exclusion of vaccines from the definition of COD to exclude drugs or biologicals that treat a disease. We also proposed that a vaccine must be administered to induce active, antigen-specific immunity because that is a characteristic of preventive vaccines.

Finally, we proposed to limit the definition of vaccine to those products that satisfy the conditions of being administered prophylactically, to prevent a disease, and induce active antigen-specific immunity, and that also appear on a current or previous list of vaccines compiled by FDA. FDA publishes a list of vaccines licensed for use in the United States.¹⁷ As FDA is the agency responsible for licensing vaccines, we stated our belief that if a product satisfying the previously described conditions appears on this list, it should be treated as a vaccine for the purposes of the MDRP.

We sought comment on whether the proposed definition of vaccine, for purposes of the MDRP only, appropriately distinguishes between preventive vaccines (which would satisfy the definition of vaccine and, therefore, not satisfy the definition of a COD and would not be subject to the requirements of section 1927 of the Act), and therapeutic vaccines (which would not satisfy the definition of vaccine and therefore could satisfy the definition of a COD and thus be subject to the requirements of section 1927 of the Act). Additionally, while we proposed to limit this definition to the MDRP, we sought comment on whether this

definition might result in indirect consequences for Medicaid benefits other than the prescribed drugs benefit. We also requested comment about the consequences for Medicaid of ACIP's recommending immunization with a product that would not qualify as a vaccine under this definition.

We appreciate the thoughtful comments we received on this issue. At this time, we are not finalizing the proposed regulatory definition. We are continuing to review the input provided by commenters on the proposed definition, which may inform future rulemaking on this topic.

D. Proposal To Account for Stacking When Determining Best Price— (§ 447.505)

In the proposed rule, we proposed revisions to the regulations for the determination of best price at § 447.505(d)(3) to make clearer that the manufacturer must adjust the best price for a drug for a rebate period if cumulative discounts, rebates, or other arrangements to best price eligible entities subsequently adjust the prices available from the manufacturer, and that those discounts, rebates, or other arrangements must be “stacked” for a single transaction to determine a final price realized by the manufacturer for a drug.

We described that section 1927(c)(1)(C) of the Act defines the term “best price” to mean with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, subject to certain exceptions and special rules. The implementing regulations for the determination of best price are at § 447.505. Consistent with this provision, in 2007, CMS promulgated § 447.505(e)(3) (currently § 447.505(d)(3)) to make clear that in order to reflect market transactions, the best price for a rebate period should be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.¹⁸

In the 2016 COD final rule, in response to a comment, CMS further

¹⁵ While section 1928(h) of the Act defines “pediatric vaccine” and “qualified pediatric vaccine,” those definitions do not speak to the actions of a vaccine in the human body and how and when it is used, and therefore do not help CMS determine when a product should count as a vaccine (as opposed to a drug) for purposes of the Medicaid Drug Rebate Program.

¹⁶ Beginning October 1, 2023, under section 11405 of the Inflation Reduction Act of 2022, States were required to cover approved adult vaccines recommended by the ACIP, and their administration, for many adults enrolled in Medicaid and all adults enrolled in CHIP, without cost sharing. States are required to cover COVID-19 vaccines and COVID-19 vaccine administration through September 30, 2024, for all CHIP beneficiaries and nearly all Medicaid beneficiaries. For more information on Medicaid and CHIP vaccination coverage, including on what types of CDC/ACIP recommendations are relevant to that coverage, see <https://www.medicaid.gov/sites/default/files/2023-06/sho23003.pdf>.

¹⁷ <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states>.

¹⁸ <https://www.govinfo.gov/content/pkg/FR-2023-05-26/pdf/2023-10934.pdf>.

clarified that a manufacturer is responsible for including all price concessions that adjust the price realized by the manufacturer for the drug in its determination of best price. CMS' response provided a specific example in which two best price eligible entities each receive a rebate or discounts for the same drug transaction as it moves through the supply chain, such as a rebate paid by a manufacturer to a PBM where such rebate is designed to adjust prices at the retail or provider level, and a discount to a retail community pharmacy. Each transaction adjusts the final price realized by the manufacturer for the sale of that drug. That is, all discounts, rebates, and price concessions related to that transaction, which adjust the ultimate price realized by the manufacturer, should be considered in the manufacturer's final price of that drug when determining the best price to be reported.¹⁹

We indicated that we have considered stacking, as stated in the preamble to the 2016 COD final rule, as consistent with current § 447.505(d)(3), which requires that if cumulative discounts subsequently adjust the price available from the manufacturer, they should be included in the best price calculation. We indicated that the proposed revisions to the regulatory text at § 447.505(d)(3) would make clearer that manufacturers must stack all applicable price concessions that they offer on a single sale of a covered outpatient drug, including discounts or rebates provided to more than one best price eligible entity.

We received comments both supporting and opposing the proposed revisions to § 447.505(d)(3). Based on these comments, we are not finalizing the proposal at this time. Instead, we are going to pursue the collection of additional information from manufacturers related to best price stacking methodologies to inform future rulemaking. We will continue to consider the comments regarding stacking during this time.

While we believe that some manufacturers are already using some type of stacking methodology in determining their best price, we believe it important to further understand the various ways that manufacturers are, in fact, determining their best price and the extent they are using a stacking methodology in doing so. We understand from a 2019 OIG report (Reasonable Assumptions in Manufacturer Reporting of AMPs and

Best Prices)²⁰ that about half of the manufacturers responding to the survey indicated that they did stack their price concessions in determining best price, but several indicated that they wanted additional guidance from CMS.

We intend to undertake a separate collection of information from manufacturers to help us better understand the areas in which additional guidance might be useful related to stacking methodologies. The information collection would be intended to ascertain whether a manufacturer implements any form of stacking and, if so, how that stacking is performed.

We acknowledge that we may not have all the information necessary to assess how stacking impacts manufacturers' reporting of best prices. Collecting this additional information will assist the agency in its consideration of the stacking issue and the comments submitted and may inform future rulemaking.

E. Proposal To Rescind Revisions Made by the December 31, 2020 Final Rule To Determination of Best Price (§ 447.505) and Determination of Average Manufacturer Price (AMP) (§ 447.504) Consistent With Court Order

In the proposed rule, we included a provision that would withdraw changes to our regulations found at §§ 447.504 and 447.505, based on a court order. As background, on June 19, 2020, CMS proposed regulations to address the effect of PBM accumulator adjustment programs on best price and AMP calculations (85 FR 37286) in relation to purported manufacturer financial assistance payments (that is, financial assistance payments in the form of copay coupons to patients for purposes of paying the patient cost obligation of certain drugs) by instructing manufacturers on how to consider the impact of such programs when determining best price and AMP for purposes of the MDRP. CMS proposed that the exclusions for manufacturers' financial assistance payments "apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient" (85 FR 37299). The 2020 final rule finalized this proposed change and delayed the effective date of the change until January 1, 2023, to "give manufacturers time to implement a system that will ensure the full value of assistance under their manufacturer-sponsored assistance program is passed on to the patient" (85 FR 87053).

In May 2021, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a complaint against the Secretary, requesting that the court vacate these revisions to § 447.505(c)(8) through (11) (85 FR 87102 and 87103), as set forth in the 2020 final rule. On May 17, 2022, the United States District Court for the District of Columbia ruled in favor of the plaintiff and ordered that the applicable provisions of the 2020 final rule be vacated and set aside.

In response to this court order, we proposed in this rule to withdraw the applicable changes made to the best price regulation and to also withdraw the corresponding changes to the AMP regulation to apply consistent rules for determining best price and AMP. Thus, in making this proposal, we suggested the removal of the language added to these sections as part of the 2020 final rule: §§ 447.504(c)(25) through (29) and (e)(13) through (17) and 447.505(c)(8) through (12). See 85 FR 87102 and 87103. Specifically, we proposed the removal of the phrase "the manufacturer ensures" from these provisions. As a result, these regulations would revert back to the language that has been in place since 2016.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the proposal to rescind the revisions made by the 2020 final rule because they were supportive of patient assistance programs and were concerned that the requirement that AMP and best price include such price concessions would have been detrimental to patient assistance programs (for example, manufacturer coupons) if adopted. Many commenters also suggested CMS search for alternative regulatory mechanisms to reduce impacts caused by the transfer of the value of patient assistance programs to payers through accumulator programs and consider ways to correctly account for such programs in Medicaid AMP and best price reporting for MDRP. They also emphasized that CMS should continue to explore ways to minimize the harmful impact of manufacturer coupons on beneficiaries and health care costs, specifically researching the effects of induced demand, unnecessary spending, and the role they play in the price manufacturers set for their drugs.

Response: We thank the commenters for sharing their views. Per the court decision, CMS is rescinding the applicable revisions made by the 2020 final rule. We will continue to explore other ways to protect consumers from accumulator programs that leave

¹⁹ <https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf>.

²⁰ <https://oig.hhs.gov/documents/evaluation/3188/OEI-12-17-00130-Complete%20Report.pdf>.

vulnerable patient populations with a significant cost-sharing burden once a patient exhausts a manufacturer patient benefit program.

Comment: A commenter requested that CMS rescind the portion of the 2021 Notice of Benefit and Payment Parameters (NBPP) final rule that enables plans to not count manufacturer cost-sharing assistance toward patients' annual cost-sharing limits, thereby effectively enabling the use of PBM accumulator programs, which are harmful to patients.

Response: We thank the commenter but note that this request is outside of the scope of this final rule.

Given the direction by the court's ruling to vacate and set aside the changes made by the 2020 final rule, we are finalizing as proposed to remove the language added to these sections as part of the 2020 final rule: §§ 447.504(c)(25) through (29) and (e)(13) through (17) and 447.505(c)(8) through (12).

F. Drug Classification; Oversight and Enforcement of Manufacturer's Drug Product Data Reporting Requirements—Proposals Related to the Calculation of Medicaid Drug Rebates and Requirements for Manufacturers (§§ 447.509 and 447.510)

1. Medicaid Drug Rebates (MDR) and Penalties (§ 447.509)

In the proposed rule, we included a new process to identify, notify and correct a manufacturer's drug category misclassifications. As background, we noted that section 6 of MSIAA, titled "Preventing the Misclassification of Drugs Under the Medicaid Drug Rebate Program," amended sections 1903 and 1927 of the Act to clarify the definitions for multiple source drug, single source drug, and innovator multiple source drug, and to provide the Secretary with additional compliance, oversight, and enforcement authorities regarding the manufacturers' reporting of drug product and pricing information, which includes the appropriate classification of a drug. Drug classification refers to how a drug should be classified—as a single source (S), innovator multiple source (I), or noninnovator multiple source drug (N)—for the purposes of determining the correct rebates that a manufacturer owes the States. We noted that when manufacturers misclassify their drugs in the rebate program, it can result in manufacturers paying rebates to States that are different than those that are supported by statute and regulation, and in some cases, can result in the manufacturer paying a lower per-unit rebate amount to the States.

We noted that specifically, section 1927(c)(4)(A) of the Act, "Recovery of Unpaid Rebate Amounts due to Misclassification of Drugs," was added to the statute to provide new authorities to the agency to identify and correct a manufacturer's misclassification of a drug, as well as impose other penalties on manufacturers that fail to correct their misclassifications. In general, a misclassification in the MDRP occurs when a manufacturer reports and certifies its covered outpatient drug under a drug category, or uses drug product information, that is not supported by the statutory and regulatory definitions of S, I, or N. A misclassification can also occur when a manufacturer's drug is appropriately classified, but the manufacturer is paying rebates at a different amount than required by the statute, or where the drug manufacturer's certified drug product information for the COD is also inconsistent with statute and regulation.

Although much of this law is self-implementing, we proposed a series of regulatory amendments at §§ 447.509 and 447.510 to implement and codify the statutory changes in regulation. In § 447.509, we proposed to include a new paragraph (d), "Manufacturer misclassification of a covered outpatient drug and recovery of unpaid rebate amounts due to misclassification and other penalties," to implement additional penalty and compliance authorities outlined in section 6 of MSIAA, which amended sections 1903 and 1927 of the Act.

MSIAA also amended the Act to clarify that the reporting of false drug product information and data related to false drug product information would also be subject to possible civil monetary penalties (CMPs) by the HHS Office of the Inspector General (OIG), and to provide specific new authority to the Secretary to issue CMPs related to knowing misclassifications by drug manufacturers of drug product or misreported information. We clarified in the proposed rule that these new OIG authorities were not a subject of this rulemaking.

We also noted that, under MSIAA, if a manufacturer fails to correct the misclassification of a drug in a timely manner after receiving notification from the agency that the drug is misclassified, in addition to the manufacturer having to pay past unpaid rebates to the States for the misclassified drug if applicable, the Secretary can take any or all of the following actions: (1) correct the misclassification, using drug product information provided by the manufacturer, on behalf of the manufacturer; (2) suspend the

misclassified drug, and the drug's status as a covered outpatient drug under the manufacturer's national rebate agreement, and exclude the misclassified drug from FFP (correlating amendments to section 1903 of the Act); and, (3) impose CMPs for each rebate period during which the drug is misclassified subject to certain limitations.

The Act expressly provides that the imposition of such penalties may be in addition to other remedies, such as termination from the MDRP, or CMPs under Title XI.

a. Summary of Misclassification and General Comments Relating to Proposed Regulation (§ 447.509(d)(1) Through (4))

We proposed in new paragraphs (d)(1) through (4) of § 447.509, requirements relating to the process by which the agency would identify when a misclassification of a drug has occurred in MDRP, notify a manufacturer that we have determined that a drug is misclassified in MDRP, clarify the manufacturer's responsibility to pay past rebates due to the misclassification, and indicate the penalties that may be imposed on the manufacturer.

We received several general public comments on these proposals. The following is a summary of the general comments we received and our responses.

Comment: Some commenters provided overall support of the misclassification sections of the proposed rule in § 447.509(d), as they believe it would lead to more accurate and consistent manufacturer reporting and transparency, allow CMS to be able to correct drug misclassifications, and penalize manufacturers in effective ways if they continue to misclassify their drugs and not correct their misclassifications. Other commenters expressed some level of support but raised concerns about using suspension of the drug from the MDRP as the tool for compliance with the new misclassification requirements, or about the feasibility of the timelines.

Response: We thank the commenters for their support and address the specific concerns in more detail later in this section.

Comment: Many commenters opposed various components of the proposed enforcement options under MSIAA for those manufacturers that have misclassified their drugs and continue to misclassify their drugs. The commenters stated that these proposed enforcement regulations are overly broad, and CMS lacks statutory authority to propose them.

Response: We appreciate the comments and address the specific concerns in more detail with the other comments. However, we note that the proposed regulations align with the requirements in the applicable statutes, which gives CMS statutory authority to implement these regulations.

Comment: A few commenters urged CMS to explicitly state in the final rule that manufacturers who fail to provide 340B discounts during the suspension of the drug due to the misclassification of the COD will face civil monetary penalties. The commenters also seek clear guidance on coverage and payment for 340B-eligible products in relation to Medicaid during such suspensions of the drug due to misclassification.

Response: CMPs for not providing 340B pricing are outside the scope of the rule and will not be addressed. However, regarding coverage and payment for 340B-eligible products during the period of the suspension of the COD for misclassification, manufacturers must still provide drugs through the 340B Program pursuant to 42 U.S.C. 256b, and 340B covered entities may dispense those medications to eligible patients. To the extent the patients who receive these drugs acquired under the 340B Program are Medicaid beneficiaries, FFP would not be available for the claims for these drugs as Medicaid FFP is not available for the misclassified drug or drugs of this manufacturer during the period of the suspension. States could opt to cover those claims through State-only funds.

Comment: A few commenters suggested that MSIAA can only be applied prospectively and any efforts to deem a product as misclassified or impose any penalties retrospectively cannot be done. Specifically, several commenters suggested that no misclassification can apply prior to April 18, 2019, the effective date of MSIAA.

Response: The provisions of 42 CFR 447.509(d) become effective on the effective date of this final rule. However, there is no provision in the statute which would exempt manufacturers from their responsibility of correcting their misclassification from before 2019. Manufacturers have always been responsible for accurate reporting of the classification of their drug and must certify to the completeness and accuracy of that reporting when submitting data to CMS to comply with statute and regulation, as well as the terms of the NDRA. MSIAA provided new authorities to CMS to enforce this requirement with respect to drug misclassification, including the ability

to identify and correct a manufacturer's misclassification as well as impose other penalties on manufacturers that fail to correct their misclassifications. CMS already provided guidance to manufacturers regarding MSIAA in Manufacturer Release #113 on June 5, 2020. This rule provides additional regulatory support to that guidance.

Comment: A commenter expressed concern that the proposed rule inappropriately attempts to end-run a 6-year statute of limitations. The commenter stated that CMS is attempting to apply penalties to manufacturers for drug category misclassifications that occurred for periods prior to 2Q2016. As such, the commenter stated that such claims would likely be time-barred today. The commenter also stated that what the commenter alleged to be CMS' failure to act on narrow exception request appeals in a timely manner should not result in the application of the civil monetary penalty process to drugs that may have been misclassified during such time periods.

The commenter suggested that CMS consider drug classification assumptions made by manufacturers in periods prior to 2Q2016 to have been made on their merits (to the extent not already time-barred), without summarily rejecting them because they were made prior to the establishment of the "narrow exception" process. In particular, the commenter suggested that products granted narrow exception status should be assumed to be "N" drugs prior to 2Q2016, consistent with reasonable assumptions made contemporaneously by the manufacturer.

Response: The development of a narrow exception process in the 2016 COD final rule, 81 FR 5170 (February 1, 2016) did not change the MDRP manufacturer drug classification requirements prior to the development of that process. In addition, CMS provided guidance to manufacturers regarding MSIAA in Manufacturer Release #113 on June 5, 2020.

Comment: A couple of commenters requested that CMS clarify that no manufacturer will be penalized if the manufacturer has an active and pending narrow exception request and/or appeal. Some suggested CMS should revise the definition of misclassification to make clear that the definition does not include a COD for which a manufacturer has submitted a narrow exception request but has not received a written response from CMS regarding the disposition of that narrow exception request.

Response: We agree that no penalty would apply until CMS completes the narrow exception process. We do not believe this needs to be addressed in the regulation, and no change to the definition of misclassification is needed.

b. Definition of Misclassification—§ 447.509(d)(1)

We proposed to define what constitutes a misclassification in paragraph (d)(1). As proposed at § 447.509(d)(1)(i), a misclassification in the MDRP occurs when a manufacturer reports and certifies to the agency its drug category or drug product information related to a covered outpatient drug that is not supported by applicable statute or regulation.

We also proposed in § 447.509(d)(1)(ii) that a misclassification includes a situation where a manufacturer has correctly reported and certified its drug classification as well as its drug product information for a COD but is paying rebates to States at a level other than that supported by statute and regulation applicable to the reported and certified data.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that the definition of misclassification should only apply to the drug product's classification under the MDRP and that MSIAA does not authorize CMS to include any other misreported or inaccurate drug product information that may have been reported by the manufacturer in the definition of misclassification.

These commenters also expressed concern about the phrase "any other information CMS deems necessary" in the drug product information definition. They stated that what they called this "open-ended" phrase may result in the inclusion of drug product information in the definition of misclassification to exceed the authority granted in MSIAA. They suggested "drug product information" should be deleted from 447.509(d), but if not, the "open-ended" language in the definition of drug product information should be removed.

Response: We believe that drug product information can be included in the definition of misclassification. The statute does not define drug misclassification, and we believe the Congress intended the term misclassification to include any incorrect drug product information reported by the manufacturer, including but not limited to inaccurate drug category. Section 1927(c)(4)(B)(ii)(I) of

the Act provides the Secretary with the authority to use drug product information reported by a manufacturer to correct a drug misclassification. Moreover, section 1927(b)(3)(C)(iii) of the Act subjects a manufacturer to CMPs if it misclassifies a COD, such as by knowingly submitting incorrect drug product information, or if the manufacturer pays rebates at a level other than that associated with the drug's classification. This provision clarifies that incorrect drug product information constitutes a misclassification under section 1927(b)(3) of the Act. Through statutory construction, it implies that incorrect drug product information in section 1927(c)(4) of the Act is considered a misclassification as well. Thus, we are including drug product information in the definition of misclassification.

As addressed in the drug product information section, we agree that the phrase "any other information CMS deems necessary" should be removed from the drug product information definition. Therefore, we have removed this phrase in this final rule.

Comment: One commenter noted that the proposed definition omits any mention of the extent to which the manufacturer had to have knowledge of incorrect drug product information reporting that is necessary to give rise to the sanctions contemplated by the statute. They suggested that the regulation should clearly require that the manufacturer knowingly misclassified the drug.

Response: Section 1927(d)(4) of the Act expressly states that a drug misclassification can occur without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made. It is the legal responsibility of the manufacturer to report and certify the correct classification of its covered outpatient drugs as well as the drug product information associated with those covered outpatient drugs.

c. Manufacturer Notification by the Agency of Drug Misclassification— § 447.509(d)(2)

We proposed at § 447.509(d)(2) that if the agency makes a determination of a misclassification, the agency would send a written and electronic notice to the manufacturer, which may include a notification that past rebates are due. The manufacturer would have 30 calendar days from date of the notice to submit the corrected drug product information as well as any additional drug product and pricing information necessary to calculate its rebate

obligations to the States. For example, if a manufacturer misclassified a drug as an N when it should have been an S or I, then the manufacturer must submit the correct drug category as well as the drug's "best price" data for the period or periods during which it was misclassified because that data is required to calculate rebate obligations applicable to S or I drugs, but not N drugs. Once the information is changed in the MDP system, the manufacturer must certify the data.

Upon notification by CMS that the manufacturer's information was updated in the system, we proposed that the manufacturer certify the applicable price and drug product data. We proposed that the manufacturer must correct the misclassification and respond to the agency's request to certify the information in the system within that same timeline of 30 calendar days from the date of the original notification to the manufacturer of the misclassification.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters raised concerns that the proposal regarding the 30-day period for manufacturers to correct misclassification is unreasonable and exposes manufacturers to enforcement action with potential severe consequences and request that CMS allow manufacturers more than 30 days post notification to provide and certify data. One commenter suggested that CMS should liberally provide for reasonable extensions to accommodate complex reclassification and payment obligations.

Response: We believe that the 30-day period is sufficient in most circumstances for manufacturers to correct and certify a data field. Misclassification can affect the amount of rebates owed by manufacturers to States, so it is important that it be addressed in a timely manner. In other circumstances, manufacturers can informally request extensions. Accordingly, if there are extenuating circumstances that result in the manufacturer not being able to make the change within 30 days, they may request an informal extension of this deadline as well.

Comment: Some commenters urged CMS to adopt into the regulation a dispute resolution process because they believe it is unfair that CMS can solely determine if a misclassification occurred. Other commenters suggested a collaborative process or a process by which manufacturers are afforded the opportunity to investigate and validate

suspected misclassifications with the Agency before the start of the corrective action. They recommend that the 30-day correction period start once the manufacturer has validated with the Agency that a correction is needed.

Response: This misclassification process that was established in MSIAA does not provide for a specific dispute resolution process for misclassified drugs. CMS is implementing what the Congress set forth, which did not propose a dispute resolution process. However, we will take this suggestion into consideration for future rulemaking.

d. Manufacturer Payment of Unpaid Rebates Due to Misclassification— § 447.509(d)(3)

Once a determination that a misclassification has occurred in § 447.509(d)(1) and the manufacturer has been notified of the misclassification in accordance with the proposed process steps at § 447.509(d)(2), we proposed in § 447.509(d)(3) the process by which manufacturers would pay unpaid rebates to the States resulting from a misclassification of a drug in the MDRP. Specifically, we proposed that a manufacturer must pay to each State an amount equal to the sum of the products of the difference between: the per unit rebate amount (URA) paid by the manufacturer for the COD to the State for each period during which the drug was misclassified, and the per URA that the manufacturer would have paid to the State for the COD for each period, as determined by the agency based on the data provided by the manufacturer under proposed paragraph (d)(2), if the drug had been correctly classified by the manufacturer, multiplied by the total units of the drug paid for under the State plan in each period.

Consistent with section 1927(d)(4)(A) of the Act, we proposed in § 447.509(d)(3)(i) a requirement for manufacturers to pay these unpaid rebate amounts and proposed to codify at § 447.509(d)(3) the timeframe by which the manufacturer must pay the unpaid rebates to the States for the period or periods of time that such COD was misclassified, based upon the proposed URA provided to the States by the agency for the unpaid rebate amounts. Specifically, we proposed that such rebates be paid to the States by the manufacturer within 60 calendar days of the date of the notice that is sent by the agency to the manufacturer indicating that the drug is misclassified and specifies that it is the manufacturer's burden to contact the States and pay the rebates that are due. We also proposed

that a manufacturer would be required to provide documentation to the agency that all past due rebates have been paid to the States within the 60-calendar-day timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the idea that manufacturers must pay unpaid rebates that result from the correction to misclassifications. One commenter recommended CMS clarify that this is not limited to the previous 12 quarters.

Response: We appreciate the support and agree that past due rebates from manufacturers to States for misclassified drugs are not limited to just the previous 12 quarters. Manufacturers are responsible for providing accurate information to CMS for their CODs for the entire amount of time that the COD is reported in the system, and if the inaccuracy of the reported drug product information goes back more than 12 quarters, manufacturers should address it back to the beginning of the reporting of the incorrect drug product information.

Comment: A couple of commenters suggested that the payment of unpaid rebates cannot go back further than 10 years since the manufacturer record retention requirement is 10 years. They noted that it might be difficult to meet this requirement in circumstances where the drug was determined to be misclassified more than 10 years ago.

Response: There is no time limit in section 1927 of the Act regarding manufacturers paying unpaid rebates back to States, whether for misclassification of the drug or for other reasons. In other words, there may be several reasons why a manufacturer may owe States past due rebates, and that is not necessarily limited to drug misclassifications. We note that 42 CFR 447.510(f) does include a 10-year record keeping requirement for manufacturers with respect to their price reporting. However, there are also provisions in that section that require record keeping beyond the 10-year period in certain circumstances, including situations in which the records are subject to a government investigation or audit relating to pricing data of which the manufacturer is aware (so long as that investigation or audit began within the 10-year time period).

Comment: A few commenters expressed concerns about a manufacturer's ability to meet the 60-day requirement to pay owed rebates for misclassified drugs due to the volume of rebate invoices they already receive

from States under the MDRP and would further receive under this provision. Commenters also stated that 60 days is an insufficient amount of time to confirm a drug has been misclassified, collect and submit the information to CMS, calculate any owed rebates to the States, make the payment to the States, and provide documentation to CMS that it is completed.

The commenters suggested the payment of any rebates due to misclassification should be facilitated through the same mechanism currently used for Medicaid rebates so they would be processed as prior quarter adjustments. Another suggested that 180-day periods be allowed to pay rebates due to misclassification (with reasonable extensions to accommodate complex reclassification and payment obligations) since that timeframe would be more reasonable. Another commenter requested CMS provide manufacturers with the opportunity to start the 60-day timeframe when the URA is updated in the MDP system.

Response: We disagree with the commenters' contentions and believe that the assessment of a COD, and any resulting rebate payments, can be made by the manufacturers within the 60-day limit. Manufacturers must process revised rebates, which includes calculating any updated pricing statistics, such as best price and AMP, report those to CMS and certify them, and then use those revised data to calculate new URAs for the misclassified drug. Manufacturers must then use those data to adjust the rebates that they have already paid to the State for the misclassified drug and pay those adjustments to the State. We believe that a process separate from the normal quarterly rebate cycle would help States ensure that the payments were made for these misclassified drugs and could be tracked by States.

A separate process can ensure there is a collection for rebates due for past quarters resulting from the misclassification. We also believe that processing these requests for rebates for misclassified drugs as the misclassification occurs rather than waiting for a quarterly rebate invoice process ensures that the misclassification is handled timely and appropriately. Accordingly, we believe a manufacturer can address a misclassification and any subsequent rebate payment within the 60-day timeframe.

e. Agency Authority To Correct Misclassifications and Additional Penalties for Drug Misclassification—§ 447.509(d)(4)

We proposed § 447.509(d)(4), consistent with section 1927(c)(4)(B) of the Act, which would allow CMS to correct the drug's misclassification on behalf of the manufacturer, as well as provide a plan of action for enforcement against the manufacturer. Specifically, we proposed at § 447.509(d)(4) that the agency would review the information submitted by the manufacturer based on the notice sent under proposed paragraph (d)(2), and if a manufacturer fails to correct the misclassification and to certify applicable pricing and drug product information within 30 calendar days after the agency notifies the manufacturer of the misclassification, and/or fails to pay the rebates that are due to the States as a result of the misclassification within 60 calendar days of receiving such notification, the agency may do any or all of the following:

- Correct the misclassification of the drug in the system, using any pricing and drug product information that may have been provided by the manufacturer, on behalf of the manufacturer;
- Suspend the misclassified drug, and the drug's status as a COD under the manufacturer's rebate agreement from the MDRP, and exclude the misclassified drug from FFP in accordance with section 1903(i)(10)(E) of the Act;
- Impose a Civil Monetary Penalty (CMP) for each rebate period during which the drug is misclassified, not to exceed an amount equal to the product of:
 - The total number of units of each dosage form and strength of such misclassified drug paid for under any State plan during such a rebate period; and
 - 23.1 percent of the AMP for the dosage form and strength of such misclassified drug for that period.

We also proposed at § 447.509(d)(4)(iv) to indicate that, in addition to the actions described previously in the proposed rule, we may take other actions or seek additional penalties that are available under section 1927 of the Act (or any other provision of law), against manufacturers that misclassify their drugs including referral to the HHS OIG and termination from the MDRP. We noted that section 1927(b)(4)(B)(i) of the Act provides that the Secretary may terminate a manufacturer from the program for violation of the rebate agreement or

other good cause. Furthermore, section 1927(c)(4)(D) of the Act indicates that other actions and penalties against a manufacturer for misclassification of a drug include termination from the program. Therefore, we proposed that a manufacturer may be subject to termination from the program if it fails to meet the agency's specifications for participation in the MDRP program as proposed when it is in violation of section 1927(b)(4)(B)(i) or (c)(4)(D) of the Act. This includes failing to correct misclassified drugs as identified to the manufacturer by the agency and continuing to have one or more drugs suspended from MDRP because of the lack of certification of the correct drug classification data in the system.

We noted that as provided in section 1927(b)(4)(C) of the Act, a manufacturer with a terminated NDRA is prohibited from entering into a new NDRA for a period of not less than one calendar quarter from the effective date of the termination until all of the above or any subsequently discovered violations have been resolved unless the Secretary finds good cause for an earlier reinstatement. In accordance with section 1927(b)(4)(B)(ii) of the Act, and section VII.(e) of the NDRA, termination shall not affect the manufacturer's liability for the payment of rebates due under the agreement before the termination effective date. Consequently, invoicing by States may continue beyond the manufacturer's termination from the program for any utilization that occurred prior to the effective date of the termination.

We also clarified that suspension of a drug under this section as a COD due to a misclassification would not affect its status as a reimbursable drug under Medicare Part B or a drug covered under the 340B Program.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed support for CMS to be able to reclassify a misclassified drug. Other commenters raised concerns about CMS being able to do this and suggested having a collaborative process or a dispute resolution process if the manufacturer disagrees.

Response: We acknowledge the commenter's concern but note that manufacturers can collaborate with CMS under the process set forth in the proposed rule. As stated previously, under § 447.509(d)(2), when a manufacturer is notified of a misclassification, it must provide the information necessary to correct the misclassification. Upon receipt, CMS

will make the corrections, and then the manufacturer must certify the applicable price and/or drug product information entered by CMS. This process allows for manufacturers to work with CMS to ensure the information in the system is accurate.

It is only when the manufacturer takes no action to correct the misclassification that section 1927(C)(4)(B)(i) of the Act now gives CMS authority to correct misclassifications on behalf of the manufacturer. Thus, the regulation gives the manufacturer time to correct the misclassification and work with CMS to ensure the information is accurate, but if they do not, in accordance with the statute, CMS can use pricing and drug product information provided by the manufacturer to make the correction. This is one of several actions CMS may take if the manufacturer has not corrected the misclassification in a timely manner.

In the Medicaid Drug Rebate Program Data Guide (July 2023), we clarified that any change made in the MDP system, including any change made by CMS, must be certified by the manufacturer in order for the changes to be effective in the MDP system. This applies to any changes made pursuant to CMS' authority in § 447.509(d)(4). Given the comments and concerns raised, we are amending the regulatory text in § 447.509(d)(4)(i) in this final rule to be consistent with this guidance and to clarify that any changes made by CMS must be certified by the manufacturer. Manufacturers will be given 30 days to certify those changes; if they do not, then CMS may take other authorized actions against the manufacturer.

Finally, we note that the process to address misclassifications was established in MSIAA, and no dispute process was included in the statute. That said, we will consider such a process for future rulemaking.

Comment: Some commenters mentioned that if CMS and the manufacturer are in a disagreement regarding a misclassification, CMS should not revise the pricing data points. They suggest this should be part of future rulemaking.

Response: Pursuant to the statute, CMS has authority to correct a misclassification using the drug product information provided by the manufacturer on behalf of the manufacturer. The enforcement provisions in section 1927(c)(4)(B)(ii) of the Act provide options for CMS to take action when a manufacturer fails to correct a misclassification. CMS' current process within the MDP system requires the manufacturer to certify any change made in the MDP system. However,

CMS may certify changes on behalf of the manufacturer and would do so in this specific situation. We do not believe any additional regulatory changes are necessary based on these comments.

Comment: Some commenters expressed support of CMS being able to impose the enumerated penalties in § 447.509(d)(4). Several raised concerns specifically about the use of the suspension penalty. Some provided suggestions for other enforcement actions, such as keeping the drug available to Medicaid beneficiaries and taking other actions such as the manufacturer covering the entire cost of the drug during the suspension period, increasing the maximum civil monetary penalty that may be imposed, or only imposing the suspension after repeated failure by the manufacturer to correct the misclassification. One commenter suggested the suspension should only be imposed if the misclassification has a material impact on rebates.

Response: We appreciate the suggestions regarding enforcement actions and the concerns that are raised about suspensions specifically. The statute sets forth several alternative penalties, including CMS making the correction on behalf of the manufacturer, civil money penalties, and suspension of the misclassified drug. CMS has incorporated these options into § 447.509(d)(4) and provides for flexibility for which penalties will be imposed on the manufacturer. As noted previously, misclassifications of CODs that occurred prior to 2019 must be corrected and must be done so in accordance with the provisions in § 447.509(d). There is no provision in the statute which would exempt CODs from these provisions if they were misclassified before 2019. If the manufacturer does not take such actions to correct misclassifications of their CODs, the penalties contained in § 447.509(d)(4) will apply.

Comment: A commenter supported the proposed enforcement actions and penalties as long as those are limited to data within the 10-year retention period.

Response: As noted in other responses to comments, the reporting requirements under section 1927 of the Act are not limited to 10 years and, as such, changes may be necessary to correct misclassifications that were reported more than 10 years ago. In the absence of guidance and adequate documentation to the contrary, manufacturers may make reasonable assumptions that are consistent with the requirements and intent of section 1927 of the Act and Federal regulations for reporting data for time periods prior to

10 years if they did not retain documents. However, if manufacturers do not take the actions set forth in § 447.509(d)(2) and/or (3), the penalties in § 447.509(d)(4) may be applied.

f. Transparency of Manufacturers' Drug Misclassification—§ 447.509(d)(5)

We proposed § 447.509(d)(5) to indicate that the agency would make available on a public website an annual report as required under section 1927(d)(4)(C)(ii) of the Act on the COD(s) that were identified as misclassified during the previous year. This report would include a description of any steps taken by the agency with respect to the manufacturer to reclassify the drugs, ensure the payment by the manufacturer of unpaid rebate amounts resulting from the misclassifications, and disclose the use of the expenditures from the fund created in section 1927(b)(3)(C)(iv) of the Act.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS' proposal that to meet the requirements of section 1927(c)(4)(C)(ii) of the Act, CMS will provide public notice of misclassification of drugs through annual reporting on a public website. One commenter questioned whether the report will include drug pricing information.

Response: We appreciate the support of CMS' proposal. For the question about including drug pricing information, we will not include such information. The report will only include items that were used in making the determination that the drug was misclassified, which will not include any proprietary or confidential pricing information. Instead, as included in the proposed rule, the report will include the CODs that were identified as misclassified, any steps taken by CMS to reclassify the drugs and ensure payment of unpaid rebate amounts, and a disclosure of the expenditures of the funds created under section 1927(b)(3)(C)(iv) of the Act.

After consideration of public comments on this provision, we are finalizing § 447.509(d) as proposed with the exception of making a modification to proposed § 447.509(d)(4)(i), which will be amended to add the following language at the end of that section: "In such case, the manufacturer must certify the applicable correction within 30 calendar days."

2. Requirements for Manufacturers Relating to Drug Category—Requirements for Manufacturers (§ 447.510(h))

Section 447.510(h) describes the process by which a manufacturer's NDRA would be suspended after a manufacturer fails to report information, which includes drug pricing and drug product information, as described in section 1927(b)(3)(A) of the Act, within a specified timeframe. This drug product and pricing information includes AMP, best price, and drug product information as described in the proposed definition of drug product information included in this rule.

Specifically, the new paragraph § 447.510(h)(1) (originally § 447.510(i) in the proposed rule), proposed that if a manufacturer fails to provide the information required to be reported to the agency under § 447.510(a) and (d), the agency will provide written notice to the manufacturer of the failure to provide timely information and provide a deadline by which such information must be reported. If the manufacturer does not report the information within 90 calendar days after that deadline, the manufacturer's rebate agreement will be suspended for all CODs furnished after the end of the 90-calendar-day period. Further, the rebate agreement will remain suspended for Medicaid until such information is reported in full and certified, but not for a period of less than 30 calendar days. This section also proposed that continued suspension of the rebate agreement could result in termination for cause.

As noted in the proposed rule, during the period of the suspension, the CODs of the manufacturer are not eligible for Medicaid coverage or reimbursement and Medicaid FFP. However, the manufacturer must continue to offer its CODs for purchase by 340B eligible entities, and reimbursement availability for such drugs under Medicare Part B would not change because, while suspended for purposes of the MDRP, the Medicaid drug rebate agreement with the manufacturer would remain in effect for purposes of Medicare Part B reimbursement and the 340B Program.

Under proposed § 447.510(i)(2), we indicated that the agency would notify the States 30 calendar days before the effective date of the manufacturer's suspension. In the preamble to the proposed rule, we noted that the suspension of a manufacturer's agreement, and loss of the availability of FFP for a period of time, would likely mean that these manufacturer's drugs would not be available to Medicaid beneficiaries during the period of the

suspension. We indicated that the 30-day notice would give States time to work with beneficiaries and their prescribers to transition to other covered outpatient drugs that would meet the clinical needs of the beneficiaries during the suspension period. We also stated our belief that the intermediate step of suspension rather than termination should be sufficient incentive for manufacturers to report pricing and product information within the statutory and regulatory requirements, without initially resorting to termination, which means that a manufacturer's drug could be unavailable to beneficiaries for a possible longer period of time. We also stated that we believe the proposed process provided clear implementation of the statutory authority to suspend a manufacturer's rebate agreement in the event of a failure to provide timely information and would hopefully incentivize manufacturers to ensure the timely reporting of pricing and drug product information, which would further the efficient and economic operation of the MDRP.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters provided overall support of the proposed rule in § 447.510(i).

Response: We thank the commenters for their support.

Comment: Several commenters expressed opposition to the proposed suspension regulations in general or to specific provisions within the proposed regulations.

Response: We appreciate the comments and note that the proposed regulations align with the requirements in the applicable statutes.

Comment: Several commenters urged CMS to explicitly state in the final rule that manufacturers who fail to provide 340B discounts during the suspension of the NDRA will face civil monetary penalties. Commenters also seek clear guidance on coverage and payment for 340B-eligible products in relation to Medicaid during such suspensions.

Response: CMPs on manufacturers for not providing 340B pricing is outside the scope of the rule and will not be addressed. However, regarding coverage and payment for 340B-eligible products during the period of the suspension of the COD for misclassification, manufacturers must still provide drugs through the 340B Program pursuant to 42 U.S.C. 256b, and 340B covered entities may dispense those medications. To the extent the patients who receive these drugs acquired under

the 340B Program are Medicaid beneficiaries, there would be no FFP available for the claims for these drugs as Medicaid FFP is not available for the misclassified drugs of this manufacturer during the period of the suspension. States could opt to cover those claims through State-only funds.

Comment: A commenter suggested that while CMS' ability to suspend NDRA's might prompt quicker pricing data disclosures, it does not guarantee their accuracy; thus, CMS should audit suspicious claims.

Response: We appreciate the concern. Under section 1927(b)(3)(A) of the Act, manufacturers have always been required to accurately report their data to CMS, and in a timely manner as prescribed by statute. Upon submitting their data, manufacturers certify their completeness and accuracy. If a manufacturer subsequently needs to adjust their pricing or product data, it may do so within specified periods of time and under certain conditions, and may also adjust rebates paid to States, if applicable. If CMS suspects that the manufacturer's data is not complete or inaccurate, CMS will contact the manufacturer to inquire about the data's completeness or accuracy, or if there are still questions about the completeness or accuracy of the data, the manufacturer can be referred to the OIG.

Comment: Some commenters suggested CMS provide a weekly file or use another system to provide the updated suspended manufacturer information on a more timely basis.

Response: For terminations of manufacturers from the program, States are given a 30-day notice through a notification system, and such terminations are noted at <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html>. CMS will use the same type of process to notify affected parties of suspensions of manufacturer rebate agreements, and the status of such suspensions.

Comment: Many commenters suggested that providing a 30-day notice to States regarding an upcoming suspension is too short. They expressed concern about the impact on patient care. Others noted that it is unclear how long the suspension will last, which impacts a State's decision on coverage of a suspended manufacturer's covered outpatient drugs.

Response: We provide a 30-day notice for terminations and believe that it makes sense for this to be consistent for suspensions. After the minimum 30-day suspension, the suspension can end as

soon as the late information is reported to CMS, CMS has reviewed for completeness, and the manufacturer certifies the data. We also note that the length of the suspension depends on how soon the manufacturer reports the data.

Comment: Some commenters expressed concerns over CMS' proposed 90-day window for manufacturers to provide information that was not received by the statutory deadline prior to suspension. They expressed a need for flexibility and requested additional time for data review and validation.

Response: The statute does not allow for flexibility in the timeline, and we believe the timeline is reasonable. The statute states that if the information is not reported within 90 days of the imposed deadline, the manufacturer's rebate agreement shall be suspended. Manufacturers are expected to report on a timely basis; this proposal provides an additional 90 days after missing a deadline to report prior to suspension.

Comment: Several commenters expressed concern regarding the requirement that CMS suspend a manufacturer's NDRA for a minimum of 30 days. Commenters also advocated for alternative compliance measures such as fines or extended deadlines.

Response: We appreciate the comments but note that a suspension is required by the statute. The statute requires the suspension for no less than 30 days. We proposed that the manufacturer is suspended until the date the information is reported to the agency and the agency reviews for completeness but not for a period of fewer than 30 days.

The Secretary is authorized to impose penalties for late reporting. CMS notes that the statute authorizes penalties for each day in which the information has not been provided, and if such information is not reported within 90 days of the imposed deadline, the agreement shall be suspended. Penalties are assessed by the OIG and are outside the scope of this rule; our rule addresses the situation once the suspension phase is reached.

Comment: Several commenters noted that the loss of FFP could result in an increased cost to the State if the products are covered with State-only funds, which may result in States not covering the products and effectively end coverage of these products. Some suggested that the claims should not lose eligibility for Federal funding or should be eligible for an additional 60 days after notice of suspension.

Response: As noted in our preamble in the proposed rule, during the period of a suspension, the claims for the

suspended drug are not eligible for FFP. States may cover the product using State-only funds if they choose or may choose to not cover the products while the product is suspended. This is consistent with other coverage decisions of products for which there is no FFP. Our hope is that manufacturers will choose to report their required information in a timely manner and not be subject to this suspension.

Comment: One commenter requested CMS clarify if FFP would be available for crossover Part B claims for these drugs.

Response: FFP would not be available for Part B crossover claims for dual eligibles. As we noted in the proposed rule, reimbursement availability under Medicare Part B would not change. Thus, our rule does not impact Medicare coverage or reimbursement. However, for crossover purposes, the claim would not be eligible for FFP if the Medicaid program made any payment on the claim. In addition, the claim would not be eligible for manufacturer rebates.

After consideration of public comments on this provision, we are finalizing this provision as proposed.

G. Proposals Related to Amendments Made by the American Rescue Plan Act of 2021—Removal of the Manufacturer Rebate Cap (100 Percent AMP)

In the proposed rule, we added provisions that would make conforming changes to our regulations based on section 9816 of the American Rescue Plan Act (ARP) of 2021, which sunsetted the limit on maximum rebate amounts for single source and innovator multiple source drugs by amending section 1927(c)(2)(D) of the Act by adding "and before January 1, 2024," after "December 31, 2009". In accordance with section 1927(c)(3)(C)(i) of the Act and the special rules for application of the provision in sections 1927(c)(3)(C)(ii)(IV) and (V) of the Act, this sunset provision also applies to the limit on maximum rebate amounts for CODs other than single source or innovator multiple source drugs.

We noted that section 2501(e) of the Affordable Care Act had amended section 1927(c)(2) of the Act by adding a new subparagraph (D) and established a maximum on the total rebate amount for each dosage form and strength of a single source or innovator multiple source drug at 100 percent of AMP, effective January 1, 2010. This limit or "rebate cap" on maximum rebate amounts was codified at § 447.509(a)(5) for single source and innovator multiple source drugs, effective January 1, 2010. This limit was later extended to apply

to drugs other than single source or innovator multiple source drugs by section 602 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74, enacted November 2, 2015) (BBA 2015), which amended section 1927(c)(3) of the Act to require that manufacturers pay additional rebates on each dosage form and strength of such drugs if the AMPs of such drugs increase at a rate that exceeds the rate of inflation. This provision of BBA 2015 was effective beginning with the quarter starting on January 1, 2017, and the limit on maximum rebates for drugs other than single source or innovator multiple source drugs was added at § 447.509(a)(9).

To align § 447.509 with section 1927(c)(2)(D) of Act, as amended by the American Rescue Plan Act of 2021, and sections 1927(c)(3)(C)(i), (ii)(IV), and (ii)(V) of the Act, we proposed to make conforming changes to § 447.509 to reflect the removal of the maximum rebate amounts for rebate periods beginning on or after January 1, 2024. Specifically, we proposed to amend § 447.509(a)(5) and (9) to state that the limit on maximum rebate amounts applies to certain timeframes, which, for all drugs, ends on December 31, 2023. That is, no maximum rebate amount would apply to rebate periods beginning on or after January 1, 2024.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters commended CMS' proactive steps in aligning the regulations with the ARP provision to remove the manufacturer rebate cap by January 1, 2024. One commenter indicated that while they support the proposed change to regulation on the manufacturer rebate cap, they also believe the Secretary should be given flexibility to reduce Medicaid inflation rebate amounts owed under the MDRP for drugs in shortage, consistent with a separate policy enacted under the Inflation Reduction Act for rebate amounts owed under the Medicare Prescription Drug Inflation Rebate Programs.

Response: We appreciate the support for the revisions made to the regulation to remove the manufacturer rebate cap. As for the comment regarding drug shortages, there is no statutory authority for the Secretary to reduce rebate amounts or “cap” rebates with respect to the MDRP in cases when a drug is in shortage.

Comment: A commenter raised concerns that the proposed rule prompts questions about the 340B Program's “penny pricing policy,” potentially

leading to negative ceiling prices, and how that aligns with the intention to penalize manufacturers for rapid price hikes. Specifically, the commenter requested that CMS work with HRSA to clarify the impact of this provision on HRSA's “penny pricing policy,” which requires that when the ceiling price calculation at 42 CFR 10.10(b) results in an amount less than \$0.01, the 340B ceiling price will be \$0.01. The commenter stated that the current policy needs to be addressed given that, beginning January 1, 2024, the ceiling price calculation for the 340B Program could be a negative number substantially lower than \$0.01.

Response: This comment is outside of the scope of this rule. HRSA administers the 340B Program and developed the policy referred to as “penny pricing” when the ceiling price (the maximum price a manufacturer may charge a 340B covered entity) is zero. We note that while CMS does not administer the 340B Program, HRSA and CMS often work together when statutory changes to the MDRP may affect the 340B Program. These comments have been shared with HRSA.

Comment: A commenter requested that CMS adopt what the commenter considers to be a “standard” definition of “rebate,” that would ensure that rebates under the MDRP do not surpass the State Medicaid program's payment for a drug, eliminating potential constitutional concerns and ambiguities. The commenter indicated that the meaning of “rebate” is compelled not only by the plain language of the statute, but also by constitutional doctrines. The commenter stated that the Takings Clause of the Fifth Amendment to the United States Constitution (Takings Clause) supports this meaning because, otherwise, manufacturers could be deprived of the economic value of their drugs and, in some cases, even forced to pay States to dispense or administer their drugs to Medicaid recipients. Furthermore, the commenter indicated that Federal courts have consistently recognized that “completely depriv[ing] an owner of ‘all economically beneficial us[e]’ of her property,” or “reduc[ing] to zero” the economic value of something, such as a drug product, would constitute a taking, which presupposes, a fortiori, that making each sale cost the company more than it earns would also affect a taking. The commenter noted that the interpretation of the statute to which the commenter objects would take drug manufacturers' property based on actions (such as price increases) that took place long before the law was enacted, raising significant retroactivity

concerns that also implicate the Takings Clause.

The commenter indicated that these retroactivity concerns also implicate the Due Process Clause, which “protects the interests in fair notice and repose that may be compromised by retroactive legislation.” The commenter noted that drug manufacturers made business decisions years ago based on their understanding that they would supply drugs at a discount under the MDRP, not pay States to dispense or administer their products to Medicaid recipients. The commenter stated that if the agency were to stray from the ordinary meaning of “rebate,” that would effectively impose a potential penalty without providing manufacturers with the requisite “fair warning of the conduct [the] regulation prohibits or requires.” The commenter recommended CMS codify in § 447.509 that, irrespective of the sunset of the statutory AMP rebate cap, there is a separate and distinct natural limit on MDRP rebates stemming from the ordinary meaning of the term “rebate” that does not permit such rebates to exceed State purchase prices. The commenter recommended CMS address this directly and adopt this ordinary meaning of the term “rebate” by regulation so that there is no ambiguity on this point among the State Medicaid programs.

Response: The ARP did not define rebate for purposes of the MDRP, and CMS is not defining the term rebate as part of this final rule. Furthermore, the amount of the rebate that is paid by the manufacturer is not solely driven by the statute's removal of the cap, but also by how much a manufacturer increases its drug prices, as reflected by changes in the AMP, compared to the rate of inflation.

After consideration of public comments on this provision, we are finalizing as proposed.

H. Proposal To Clarify § 447.509(a)(6), (7), (8), and (9) and (c)(4) With Respect to “Other Drugs”

In the proposed rule, we included a provision that would replace each appearance of the term “noninnovator multiple source drug(s)” in § 447.509 with “drug(s) other than a single source drug or an innovator multiple source drug.” As background, we noted that section 1927(c) of the Act describes how the unit rebate amount (URA) is determined for a COD. We also noted that there is a defined calculation of the applicable basic rebate and additional rebate for a COD that is either a single source drug or innovator multiple source drug at sections 1927(c)(1) and (2) of the Act, and a different defined

calculation for “other drugs,” that is, a COD that is a drug other than a single source drug or an innovator multiple source drug at section 1927(c)(3) of the Act.

We provided background in the proposed rule explaining that section 1927(c)(3) of the Act, titled “Rebate for other drugs,” describes in subsections (c)(3)(A) and (B) the basic rebate calculation for CODs other than single source drugs and innovator multiple source drugs. We noted that section 1927(c)(3)(C) of the Act describes the additional rebate calculation for CODs other than single source drugs or innovator multiple source drugs, explaining that the statute makes it clear that rebates are applicable to all CODs, whether they are single source drugs, innovator multiple source drugs, or drugs other than such drugs.

We also noted that manufacturers are required to report all of their CODs in the MDRP reporting system and must select the appropriate drug category for each (that is, S, I, or N). Since the beginning of the MDRP, the term noninnovator multiple source drug, and its abbreviation (N), have been used very generally to identify a COD other than a single source drug or an innovator multiple source drug in our system for operational purposes. Choosing N in the MDRP reporting system thus can result in capturing drugs that satisfy the statutory definition of an N drug, but also other drugs that are not single source or innovator multiple source drugs. We noted that because manufacturers are to report all of their CODs and identify the applicable drug category, all CODs other than a single source drug or an innovator multiple source drug should be identified with the drug category of N, regardless of whether they satisfy the definition of noninnovator multiple source drug.

We noted that in the 2007 final rule, we finalized a definition for “noninnovator multiple source drug” to clarify the distinction between multiple source drugs approved under an abbreviated new drug application (ANDA) and multiple source drugs approved under a new drug application (NDA). We also finalized that the term includes a drug that entered the market prior to 1962 that was not originally marketed under an NDA (72 FR 39162). We stated that over the years, interested parties have used the term “noninnovator multiple source drug” synonymously with “a covered outpatient drug that is a drug other than a single source drug or an innovator multiple source drug.” However, the statute specifically defines

“noninnovator multiple source drug” at section 1927(k)(7)(iii) of the Act as a multiple source drug that is not an innovator multiple source drug. We therefore noted that we believe that the regulatory definition of noninnovator multiple source drug may not fully align with the statutory definition because the regulatory definition does not capture every COD that is something other than a single source drug or an innovator multiple source drug; that is, not every “other drug” is a multiple source drug. Practically, though, we noted that while the terms “other drugs” and “noninnovator multiple source drugs” are not synonymous, they are treated so for purposes of reporting the COD in the MDRP system, because “other drugs” should be classified as N, if not an S or I drug.

As noted previously, the statute makes it clear that rebates apply to all CODs, regardless of whether they are single source drugs, innovator multiple source drugs, or something other than a single source drug or innovator multiple source drug. To align our longstanding policy and practices of identifying “other drugs” referenced in section 1927(c)(3) of the Act as N drugs, for purposes of the MDRP, we proposed to modify language in § 447.509 by replacing each appearance of “noninnovator multiple source drug(s)” with “drug(s) other than a single source drug or an innovator multiple source drug.”

We proposed to delete each appearance of “noninnovator multiple source drug(s)” in § 447.509 and replace it with “drug other than a single source drug or innovator multiple source drug(s).” The clarification was proposed to be made in § 447.509(a)(6), (7), (8), and (9) and (c)(4).

We received a public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: One commenter stated that CMS should clarify that the replacement of “noninnovator multiple source drug” with “drug other than a single source drug or innovator multiple source drug” is not intended to have any effect on the narrow exceptions process.

Response: The replacement of the term “noninnovator multiple source drug(s)” in § 447.509 with “drug(s) other than a single source drug or an innovator multiple source drug” was proposed to align the regulatory language with the statute, which requires rebates for CODs other than single source drugs and innovator multiple source drugs regardless of whether they are multiple source drugs. The proposed change was also intended

to clarify our longstanding policy and practices of identifying “other drugs” as N drugs for the purposes of the MDRP. The proposed changes in § 447.509 are not intended to change the narrow exception process.

After consideration of public comments, we are finalizing the clarifications to the language in § 447.509 as proposed. This clarification should not affect the drug category code reported in the MDRP reporting system for drugs other than single source drugs or innovator multiple source drugs. Drugs other than single source drugs and innovator multiple source drugs should continue to be reported in the MDRP system with the drug category of “N”.

I. Proposal To Establish a 12-Quarter Rebate Audit Time Limitation (§ 447.510)

In the proposed rule, we included provisions to provide a 12-quarter time limit for processes related to the initiation of rebate audits by manufacturers. As background, we noted that in accordance with sections 1927(b)(1) and 1927(c) of the Act, and section II(b) of the NDRA, manufacturers are required to pay quarterly rebates to States for the CODs dispensed and paid for under the State plan for the rebate period. Section 1927(b)(2)(B) of the Act provides that a manufacturer may audit the rebate billing information provided by the State as set forth under section 1927(b)(2)(A) of the Act on the total number of units of each dosage form, strength and package size of each COD dispensed and paid for under the State plan during a rebate period, and authorizes that adjustments to rebates shall be made to the extent that the information provided by States indicates that utilization was greater or less than the amount previously specified. For the purposes of the regulation, we noted that audit authority is intended to refer to any process a manufacturer is using to seek an adjustment to State drug utilization data under section 1927(b)(2)(B) of the Act.

We also noted that section V. of the NDRA describes how the agency operationalizes the manufacturer audit authority; that is, it describes the procedures for manufacturer dispute resolutions once an audit identifies a dispute with the utilization data (that is, number of units for any given quarter) for which States are requesting rebates using a rebate invoice.²¹ The audit/

²¹ See section V, Dispute Resolution, “Medicaid Program: Announcement of Medicaid Drug Rebate

dispute resolution processes are further discussed in a number of manufacturer releases.²² We explained that an adjustment is a correction in the number of units for any given NDC or a correction to the unit rebate amount (URA) by the labeler for any given NDC.²³ We clarified a dispute to mean “a disagreement between the labeler and the State regarding the number of units the State invoiced for any given quarter.” Finally, consistent with section 1927(b)(2)(B) of the Act, we noted that all disputes must be resolved on a unit basis only, and not on any other factor (for example, monetary amounts, percentages, etc.).²⁴ State Release Number 45 sets forth the Dispute Resolution Process for manufacturers and States to follow when engaged in a dispute. In that release, we specified that the manufacturer should notify a State of the disputed data no later than 38 days after the State’s utilization invoice is sent.

We also pointed out that while section V. of the NDRA, along with several CMS-issued program releases, addresses dispute resolution procedures for when a manufacturer identifies State drug utilization data (SDUD) discrepancies based on the audit authority at section 1927(b)(2)(B) of the Act, no law or regulation provides a specific time limitation for initiating a dispute over drug utilization data.²⁵ Thus, we indicated that we believe having an unlimited timeframe to initiate such disputes on rebates can result in manufacturer, State, and Federal resources being spent to adjudicate excessively old data and is not an efficient use of resources. We, therefore, proposed to use our authority under sections 1102 and 1902(a)(4) of the Act, which authorizes the Secretary to specify methods of administration found to be necessary for proper and efficient administration of the Medicaid program, to require efficient handling of disputes by limiting the period for manufacturers to initiate disputes, hearing requests, and audits concerning State-specified COD utilization data to

12 quarters from the last day of the quarter from the date of the State invoice. Consistent with this authority, we proposed to establish a 12-quarter time limit for manufacturers to initiate disputes, hearing requests, and audits for State-invoiced units on current rebates as well as to initiate disputes, hearing requests, and audits on rebates that have been paid in full. We proposed a time limitation to help ensure that discrepancies are identified and resolved, thereby promoting the efficient operation of the MDRP.

We recognize the potential burden for States and manufacturers to comply with a 38-day dispute initiation timeframe as mentioned in State Release Number 45; while we believe 38 days is optimal, we stated in the proposed rule that we believe that a 12-quarter timeframe is reasonable because it comports with requirements for maintenance of records on State Medicaid expenditures at § 433.32. We reminded manufacturers it also mirrors the timeline for reporting revisions to monthly AMP at § 447.510(d)(3). We also noted that there are 2-year timely claims filing deadlines under section 1132(A) of the Act, and regulations at 45 CFR 95.7, which may prohibit States from claiming FFP in these situations, unless under a good cause waiver. Therefore, we proposed to ensure the efficient handling of rebate disputes, by limiting the period for manufacturers to initiate disputes, hearing requests, or audits concerning State utilization data submitted pursuant to section 1927(b)(2)(A) of the Act to 12 quarters from the last day of the quarter from the date of the State invoice. This is consistent with our authority at section 1902(a)(4) of the Act.²⁶

Accordingly, we proposed at § 447.510(i) that a manufacturer may, within 12 quarters from the last day of the quarter from the State invoice date, initiate a dispute, request a hearing or seek an audit with a State for any discrepancy with SDUD reported under section 1927(b)(2)(A) of the Act on the State rebate invoices.

We received public comments on this proposal. The following is a summary of the comments received and our responses.

Comment: We received numerous comments supporting CMS’ proposal to impose a 12-quarter limit on manufacturers initiating disputes on

State drug utilization data, as it will streamline administrative processes, reduce burdens on States and providers, and ensure that disputes are based on recent, validated data. Additionally, commenters noted that imposing time limits on the initiation of disputes and audits streamlines the States’ management of the drug rebate program.

Response: We appreciate commenters’ support. We are focused on increasing efficiency and economy of overall MDRP resources to better facilitate the needs of Medicaid beneficiaries. We believe the time limitation on rebate disputes by manufacturers will help ensure that discrepancies are timely identified and efficiently resolved, thereby providing increased financial certainty to manufacturers and States, while promoting the efficient operation of the MDRP.

Comment: Multiple commenters opposed CMS’ proposal for a 12-quarter audit limit, citing a lack of statutory authority, and questioned CMS’ authority to implement such a requirement.

Response: We believe that a limitation on the timeline of when a manufacturer may audit comports with our policy goals and is supported by CMS’ general rulemaking authority in section 1102, as well as 1902(a)(4) of the Act, which allows the Secretary to specify such methods necessary for the proper and efficient operation of the plan. We have the responsibility of administering the MDRP and ensuring the proper and efficient operation of the Medicaid program, and establishing a timeframe limitation for manufacturer audits is consistent with this goal. Additionally, having this timeline limitation provides more financial certainty for States and Manufacturers for rebate purposes because invoices, transactions, and payments can be settled, therefore increasing stability in program operations.

Comment: Some commenters suggested that if CMS imposes a 12-quarter limit on manufacturers’ ability to dispute rebates, they should ensure the timeframe starts when manufacturers receive the State invoice. Specifically, commenters stated that the timeframe should begin when manufacturers receive the State invoice that includes the disputed utilization or when manufacturers receive detailed claims data.

Response: We continue to encourage States to respond to reasonable requests from manufacturers for claims level data, as the willingness to share data, methodologies, and resolution strategies generally leads to resolutions. However, as these requests are on an as-needed

Program National Rebate Agreement,” Final Notice, 83 FR 12770 (Mar. 23, 2018).

²² State Release 177, State Release 181, State Release 56, Manufacturer Release 115, Manufacturer Release 105, Manufacturer Release 95, and Manufacturer Release 20.

²³ <https://www.ncdp.org/NCPDP/media/pdf/WhitePaper/Medicaid-Drug-Rebate-Program-Challenges-Across-the-Industry.pdf?ext=.pdf>.

²⁴ Please see State Release 181, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/state-rel-181_42.pdf.

²⁵ <https://www.ncdp.org/NCPDP/media/pdf/WhitePaper/Medicaid-Drug-Rebate-Program-Challenges-Across-the-Industry.pdf?ext=.pdf>.

²⁶ We had also referenced section 1102 of the Act for our authority to implement this provision. Section 1102 of the Act grants the Secretary authority to promulgate regulations but not the authority to impose specific requirements and thus does not need to be cited as authority to implement this provision.

basis, we do not believe the date for which claims level details are received by the manufacturer is an appropriate date to start the dispute initiation timeline limitation.

Upon further consideration, we believe the invoice postmark date will offer the same clarity for the interested parties involved in the dispute process and will better align with established Medicaid policy. In accordance with section 1927(b)(1)(A) of the Act and the terms of the NDRA, manufacturers are required to pay a rebate to each State for all CODs of the manufacturer that were paid for in a quarterly rebate period. This section of the Act also states that such rebate payments are to be paid within 30 days of the manufacturer's receipt of the State invoice. For purposes of calculating interest on late rebate payments, previously issued guidance has noted that manufacturers have 37 calendar days as evidenced by the postmark by the U.S. Postal Service on the envelope to pay rebates before interest begins to accrue.²⁷ That is, upon receipt of a quarterly invoice, manufacturers have 37 calendar days' time from the invoice postmark date to pay rebates before interest begins to accrue on the 38th day. Therefore, to maintain consistency, we are amending the proposed language in this final rule to specify that upon receipt of a quarterly invoice, the period for manufacturers to initiate audits or disputes concerning State drug utilization data begins on the last day of the quarter from the State invoice's postmark date.

As an example, if the invoice postmark date is in the fourth quarter of 2024, then the time period to initiate a dispute ends 12 quarters after the last day of the fourth quarter of 2024, which would be the last day of the fourth quarter of 2027. If States use electronic invoicing via email, we expect States to include the invoice itself within the body of the email to a manufacturer or, at minimum, information on the number of units paid by NDC. In this case, we view the postmark date as the date on which the email is sent. Similarly, if a State sends an email with the invoice

attached, then the date when the initiation time period ends is 12 quarters from the last day of the quarter in which the email was sent. For example, if the email was sent in the fourth quarter of 2024, then the time period to initiate a dispute ends 12 quarters after the last day of the fourth quarter of 2024, which would be the last day of 4Q2027.²⁸

Comment: Some commenters expressed concerns regarding fairness and parity between manufacturers and States. While advocating for equitable treatment between manufacturers and States, some suggested either adjustments to the proposal or that CMS set forth similar time limits for similar types of requests by States or manufacturers. Some stated that because similar limitations were not placed on States, the provision is biased against manufacturers, possibly compromising accuracy and fairness in the MDRP. Additionally, a few commenters stated that manufacturers have reported receiving State rebate invoices related to decades-old utilization, and that States should have time limitations on disputes and submitting invoices to manufacturers, including limitations on the initiation of corrections or resubmissions of invoice data. These commenters stated that if manufacturers are to be time-limited in their ability to audit invoices, State Medicaid programs need to be held to a comparably limited period in which to submit rebate utilization.

Response: Section 1927(b)(2)(B) of the Act provides that a manufacturer may audit the rebate billing information provided by the State under section 1927(b)(2)(A) of the Act. This includes the total number of units of each dosage form, strength, and package size of each COD dispensed and paid for under the State plan during a rebate period. Adjustments to rebates are based on unit utilization and are authorized to the extent that the information provided by States indicates that utilization was greater or less than the amount previously specified.

States have similar equitable timelines with which to comply when

invoicing for rebates. States are required to invoice manufacturers based on the State's utilization of the manufacturer's CODs each quarter and must provide invoices no later than 60 days after the end of each quarter. Additionally, States have a 2-year timely claim filing deadline under section 1132(A) of the Act. This incentivizes States to manage and resolve disputes within this timeframe.

Disputes handled beyond this 2-year deadline create recordkeeping and fiscal issues for the States, hindering them in claiming FFP from the Federal government because the dispute exceeds the timely filing window. Resolving disputes requires the claim to be reversed and resubmitted, with States not receiving Federal match on these resubmitted claims if the dates of service fall outside the timely filing window. Therefore, we believe this timely filing deadline provides necessary incentives for States to resolve rebate disputes swiftly, as they must absorb the full cost of a rebate correction, including the portion that would otherwise be paid for through FFP.

Furthermore, the 12-quarter timeframe provided to manufacturers significantly extends the timeframe that was specified in previous guidance. State Release Number 45 and Manufacturer Release Number 11 outline the Dispute Resolution Process for manufacturers and States in rebate disputes. In these releases, we specified that manufacturers should notify a State of disputed data no later than 38 days after the State utilization data is sent. We continue to believe that manufacturers and States need to communicate as soon as possible on suspected drug unit issues to prevent and resolve disputes, preferably even before rebates are due. Establishing the 12-quarter time limitation for manufacturers to initiate disputes also aligns with the timelines permitted for manufacturers to report changes to data elements relevant to the calculation of MDRP rebate amounts. For these reasons, we continue to believe this is a balanced solution that is equitable for both manufacturers and States, providing sufficient time for dispute initiation.

Comment: One commenter expressed concern that States do not always engage effectively with manufacturers and their representatives when disputes arise. They stated that CMS should require States to respond to manufacturer-initiated disputes in a timely and effective manner and provide guidance when such disputes reach an impasse.

²⁷ Please reference Manufacturer Release 89 <https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-089.pdf>, Manufacturer Release 7 <https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-007.pdf>, and State Release 29 <https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-029.pdf>, for our policy on postmark dates.

²⁸ Please see State Release 166 <https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-166.pdf>, State Release 154 <https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-154.pdf>, and Manufacturer Release 80 <https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-080.pdf> for our policy and guidance related to postmark dates.

Response: As stated in the NDRA, both the State and the manufacturer are expected to use their best efforts to resolve a dispute within a reasonable timeframe after the State's receipt of the manufacturer's Reconciliation of State Invoice (ROSI) or Prior Quarter Adjustment Statement (PQAS). CMS expects manufacturers and States to work in partnership to resolve outstanding units in dispute. CMS has issued guidance on dispute resolutions and we encourage commenters to reference <https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-105.pdf>, <https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-095.pdf> and <https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-rel-181.pdf> for dispute related issues. In addition, as noted previously, we believe the prompt notice of disputes will encourage States to resolve these issues in a timely manner.

Comment: Several commenters emphasized that 340B Program-related audits may require more time than the proposed 12 quarters and suggest CMS should clarify and potentially adjust the rule's applicability to ensure fairness in dispute processes. Multiple commenters opposed the proposed time limit, especially concerning 340B duplicate discounts, which take longer to identify and resolve and suggest exemptions or adjustments to the rule. Certain commenters also suggested that a manufacturer be allowed to toll the time to request necessary data from the State and during certain 340B disputes.

Response: We believe that manufacturers should, within 12 quarters from the invoice postmark date, initiate a dispute with or audit of a State for any disputes they may have with regard to 340B duplicate discounts. We understand that covered entities and their contract pharmacies work with their own third-party administrators (TPAs) that help to identify prescription claims as 340B within a few days, or at most a few weeks, well within the 12-quarter timeline that was proposed. Thus, the 12-quarter timeframe should be sufficient for identification of 340B claims and any disputes that may arise. CMS issued guidance to States and other interested parties in January 2020 on Best Practices for Avoiding 340B Duplicate Discounts in Medicaid. We have previously outlined a number of

best practices that States are encouraged to consider to avoid duplicate discounts.²⁹ Additionally, our 12-quarter time audit initiation limitation aligns with HRSA's limitation of actions provision in 85 FR 80632, which specifies that a covered entity or manufacturer must file a written claim for administrative dispute resolution with HRSA within 3 years of the date of the alleged violation. Furthermore, other proposals in this regulation will help with that process, such as the proposal to include BIN/PCN numbers on Medicaid managed care enrollee identification cards for pharmacy benefits. Finally, we are finalizing that all audits must be initiated within the 12-quarter time period, not that all disputes are resolved within this timeline. We, therefore, do not believe a tolling provision is necessary.

Comment: A few commenters recommended that if CMS' proposed 12-quarter rule is finalized, it should only apply to future claims, ensuring manufacturers have time to address audits and disputes on past claims without hindrance and that State invoices received prior to the finalization of the rule would not be subject to the 12-quarter time limitation. Several commenters requested that if this policy is finalized, CMS should provide technical assistance on how to address outstanding disputes that were previously submitted but are beyond the proposed 12-quarter limit.

Response: The 12-quarter timeframe was proposed, in part, to assist States that would otherwise be required to retain their drug utilization data indefinitely to verify changes in rebate amounts resulting from retroactive manufacturer recalculations. Unlike manufacturers that can make reasonable assumptions regarding data and reporting that occur beyond their record keeping requirements, States must be able to provide specific drug unit data related to utilization. Ideally, as we have stated, disputes should be raised and resolved promptly before the invoice is paid by the manufacturers. However, manufacturers can, and do, raise disputes after payment is made, sometimes even years later. The current lack of a clear time limit means previously settled invoices, transactions, and payments might not be settled in actuality given potential new or additional disputes. Having an unlimited period to initiate disputes is inconsistent with the proper and

efficient operation of the rebate program.

In addition, when a dispute concerning a possible provider billing error arises, the passage of time makes investigation and correction by the State more difficult. Claims data may not be available after a number of years; States have reported they have trouble retrieving older claims data because system upgrades have made accessing old data and paper claims difficult or impossible. The provider may not have records for the claim anymore because the record keeping requirements do not require them to continue to retain the records, making resolving disputes unnecessarily complicated. Thus, establishing a time limit for manufacturers to initiate disputes will increase the efficiency of dispute resolutions as well as the administration of MDRP. For this reason, this provision should apply to all newly initiated rebate disputes, regardless of when the claim was processed; any claim currently in the dispute resolution process would not be affected. Rather, under the 12-quarter time limit, a manufacturer may only initiate a dispute, request a hearing, or seek an audit of a State regarding State drug utilization data during a period not to exceed 12 quarters from the last day of the quarter from the postmark date of the State invoice.

Comment: Commenters stated that CMS' 12-quarter time limit proposal lacks operational feasibility and raised concerns the proposal may limit the ability of manufacturers to ensure accuracy of drug unit utilization data received from the States.

Response: Currently, the lack of time limit on rebate dispute initiation by manufacturers is creating operational challenges for both States and manufacturers. We believe this creates long-term operational feasibility challenges for States, and burdens resources that would be better used towards patient care. During the dispute resolution process, claims-level detail is normally required from the States to assist in resolving a dispute; however, States often do not have such data available to provide to manufacturers beyond a limited timeframe. States need this source data when manufacturers request further proof to resolve disputes. Such claim data may not still be available after a fixed number of years, and the lack of a definitive timeline for initiation of disputes on drug utilization data unreasonably burdens programs.

After considering the issues raised by the commenters, we are finalizing this provision as proposed except that we are amending the language to clarify

²⁹ For best practices for avoiding 340B duplicate discounts in Medicaid, please see our January 8, 2020 Informational Bulletin <https://www.medicaid.gov/federal-policy-guidance/downloads/cib010820.pdf>.

that the 12 quarters begin based on the postmark date: A manufacturer may only initiate a dispute, request a hearing, or seek an audit of a State regarding State drug utilization data, during a period not to exceed 12 quarters from the last day of the quarter from the postmark date of the State invoice. As noted in our previous responses, we understand that in certain instances the resolution of a dispute may extend beyond this time period, and we clarify that we are not requiring that disputes are resolved within this time period.

J. Proposal Regarding Drug Price Verification Through Data Collection (§ 447.510)

Section 1927(b)(3)(B) of the Act authorizes the Secretary to “survey wholesalers and manufacturers that directly distribute their CODs, when necessary, to verify” the prices that manufacturers are reporting under section 1927(b)(3)(A) of the Act, and in accordance with § 447.510. Under this authority, we proposed rules to describe those situations when it would be considered necessary for such surveys to be sent to manufacturers and wholesalers, and the information that would be requested that we would use in order to verify the reported prices at issue. We stated our intent that the proposed surveys would help assure that Medicaid payments and applicable rebate payments for CODs are accurate.

As we noted in the preamble to the proposed rule, currently, there is no centralized process to collect specific data from manufacturers (or wholesalers) to verify prices manufacturers report to us under section 1927(b)(3)(A) of the Act. We proposed to interpret the language in section 1927(b)(3)(B) of the Act to provide authority to verify prices and charges from wholesalers and manufacturers that distribute their own drugs, including when the manufacturer distributes drugs directly to pharmacies and other providers. In other words, we stated that we believe this provision is meant to allow the Secretary to verify prices reported in both situations in which a manufacturer sells to wholesalers and/or distributes them directly on their own to purchasers.

We noted in the proposed rule that participating manufacturers are required to report and certify to CMS certain product and pricing data for each of their CODs on a monthly and quarterly basis. The COD pricing and product information is primarily used for the determination of the quarterly Medicaid drug rebates paid by participating manufacturers, but also serves as the

basis for Medicaid payment for CODs. For example, the AMPs that are reported to the agency are used in the calculation of the Medicaid Federal Upper Limits (FULs) for payment of certain multiple source CODs under section 1927(e)(5) of the Act. The 340B Program uses the AMP and the Unit Rebate Amount (which is the amount calculated to determine the quarterly Medicaid rebate for each dosage form and strength of a COD and is based in part on AMP) to calculate the 340B ceiling price. Many States require that 340B entities are paid no more than the 340B ceiling price, plus specified professional dispensing fees for CODs dispensed by 340B entities. Additionally, many State Medicaid programs use the ASP (as defined in section 1847A(c) of the Act) and the Wholesale Acquisition Cost (as defined in section 1847A(c)(6)(B) of the Act) for Medicaid payment for physician administered drugs, such as those administered in hospital outpatient departments and physician offices. Thus, we noted that it is important, particularly in the case of high cost drugs, that CMS have the ability to verify, in certain situations, the manufacturer’s submitted pricing data to ensure its accuracy, given the foregoing ramifications.

We also proposed to publish non-proprietary information that we receive from the manufacturer through the drug price verification survey. We noted our belief that our proposed drug price verification survey process and the publication of non-proprietary information, along with the NADAC that we publish for retail community pharmacy costs, should provide the public with an understanding of how CMS is implementing its authority to understand how a manufacturer determines and verifies its reported pricing for its CODs. We also noted that our proposal would also provide information on the methods manufacturers use to produce accurate price information. We indicated that Medicaid managed care plans may be able to use such public information about the accuracy of prices or charges that are collected under this process in providing drug benefits if covered under their contracts.

For the foregoing reasons, we proposed to use the statutory authority in section 1927(b)(3)(B) of the Act to collect additional information about charges and prices from manufacturers and wholesalers to verify the prices reported to us for CODs. We stated our belief that this verification is extremely important, particularly in the case of the significant number of new high-cost drugs and biologics, including cell and

gene therapy drugs, entering the market, as well as the costs and prices associated with new and different pharmaceutical preparation methods and distribution channels. We indicated that it is critical to ensure that pricing information associated with these products is accurate so that State Medicaid programs receive the full rebate amounts to which they are entitled. Assuring States obtain accurate rebates can make these products more affordable and thus more accessible to patients. In addition, we noted that the increasingly complex pharmaceutical distribution supply chain has made it more challenging for manufacturers to calculate, and for CMS and States to monitor the accuracy of, pricing information reported under section 1927 of the Act. Thus, we stated that the verification survey is needed to help ensure that such calculations are being done correctly, given the significant implications for MDRP rebate amounts and Medicaid payments.

In the preamble to the proposed rule, we underscored that the proposed drug price verification survey is not intended to limit or deny access to any of the CODs included on the survey list, assess cost effectiveness of such drugs, or supplant findings from the applicable FDA approval process. We noted that we would not be using the survey data to assess either the clinical or cost effectiveness of the COD. Furthermore, neither the selection of CODs subject to the survey, nor the information collected in response to a survey under this proposal, would impact coverage of a COD consistent with section 1927 of the Act, or supplant any of the Federal requirements established under section 1927 of the Act and the implementing regulations at 42 CFR part 447, subpart I.

Therefore, we proposed at § 447.510(k)(1) to use the authority granted to the Secretary under section 1927(b)(3)(B) of the Act to survey manufacturers with rebate agreements in effect with the Secretary to verify prices or charges for certain CODs for which drug product and pricing information is submitted under section 1927(b)(3)(A) of the Act and § 447.510, to make payment for the COD.

We appreciate the thoughtful comments we received on this issue, and we determined not to finalize the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

K. Proposals Related to State Plan Requirements, Findings, and Assurances (§ 447.518)

In the proposed rule, we included provisions to clarify the data requirements that States must submit to establish the adequacy of both the current ingredient cost and the professional dispensing fee reimbursement under Medicaid FFS. As background, we noted in the preamble to the proposed rule that section 1902(a)(30)(A) of the Act requires that States include in their State plans, methods and procedures to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area. We also reminded States that, under that authority, the Secretary issued Federal regulations at §§ 447.502, 447.512, and 447.518 that further elaborate that generally, payments to pharmacies for drugs that they dispense, and that are paid for under the State plan, are to be based on a two-part formula which consists of: (1) the ingredient cost of the drug that is dispensed based on the actual acquisition cost (AAC);³⁰ and, (2) a professional dispensing fee (PDF) for the drug based on the pharmacy's cost of dispensing.

As additional background to support our proposal, we pointed to existing policy requirements that the reimbursement formulas and any proposals to change either or both components of the reimbursement formula are subject to review and approval by CMS through the State plan amendment (SPA) process. We noted that, in SPA submissions, States must provide adequate data, such as a State or national survey of retail pharmacy providers or other reliable data (other than a survey) to support any proposed changes to either or both of the components of the reimbursement methodology. We also noted that while States are afforded the flexibility to adjust their reimbursement methodology through the SPA process in accordance with the requirements of sections 1902(a)(30)(A) and 1927 of the Act, they must substantiate how their reimbursement to pharmacy providers reasonably reflects the actual cost of the ingredients used to dispense the drug, and the actual costs of dispensing the drug, consistent with the regulatory

definitions of AAC and professional dispensing fee.

With this background, we explained in the proposed rule that recently we have seen States submit proposed changes to either or both of the components of the reimbursement methodology without adequate supporting data that reflect current drug acquisition cost prices or actual costs to dispense, which is inconsistent with applicable law and regulations. We also affirmed that the PDF should be based on pharmacy cost data, and not be based on a market-based review, such as an assessment or comparison of what other third-party payers may reimburse pharmacies for dispensing prescriptions. We stated that a State's periodic review and examination of market-based research for a comparison of what other payers reimburse for dispensing costs is an insufficient basis for determining or proposing changes to professional dispensing fees because it does not reflect actual costs to pharmacies to dispense prescriptions. We noted that States must submit adequate cost data to CMS as part of its SPA process to justify its professional dispensing fee amounts and that the data submitted cannot rely on the amounts that pharmacies are accepting from other private third-party payers.

Similarly, with respect to reimbursement of drug ingredient costs, which must be consistent with AAC, we affirmed in the preamble to the proposed rule that States must support determinations or proposed changes for ingredient cost reimbursement with adequate cost-based data. We cited previous rules and guidance, which provide ways States could establish pharmacy reimbursement methodologies, noting that the pricing benchmark that CMS makes available to States, for example the weekly NADAC files, reflect current prices. We also noted that freezing NADAC or AAC rates, and establishing a static provider reimbursement, would not be consistent with applicable laws and regulations and that reduced beneficiary access to medically necessary drugs could result if pharmacy providers are unable to purchase drugs at a rate reflective of current market conditions.

For these reasons, we proposed to clarify the data requirements that States must submit to establish the adequacy of both the current ingredient cost and the professional dispensing fee reimbursement. Specifically, a State must submit adequate *cost-based* data to support any proposed changes to either or both of the components of the reimbursement methodology and a State cannot rely on the amounts that

pharmacies are accepting from other third-party payers as a means of determining professional dispensing costs. Rather, the data that are acceptable could be a State's own survey, a neighboring States' survey, or other credible survey data that reflect the current cost of dispensing a prescription in the State (81 FR 5311). Additionally, to pay based on costs, we clarified that States need to periodically assess whether current rates being paid to pharmacies reflect current costs, noting that there is no specific requirement as to how often and when States must review their current fees. We therefore proposed to update the heading of § 447.518(d) heading to be "Data requirements" and to revise paragraph (d)(1) to specify these requirements in the regulatory text.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters provided general support statements for the proposed updates to the data reporting requirements in § 447.518 regarding State plan requirements, findings, and assurances, which will ensure patient access and appropriate pharmacy reimbursements.

Response: We appreciate receiving the comments in support of this proposal.

Comment: One commenter agreed with the proposed rule and stated that if pharmacies are unable to successfully acquire drugs at a rate reflective of the current market, there would be a ripple effect, such as limited beneficiary access due to pharmacy closures, and a negative impact on health equity for these vulnerable populations.

Response: We agree with the commenter. To ensure beneficiaries can access pharmacy services, CMS reviews each State's SPA to ensure that the reimbursement methodologies are established in accordance with applicable Federal provisions so that payments to providers are consistent with efficiency, economy, and quality of care, and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area.

Comment: Several commenters recommended that CMS consider outlining how often States should assess if the pharmacy reimbursement rates accurately reflect current costs or other mechanisms to collect reliable data to ensure rates are current and adequate for pharmacies. Another commenter stated that an annual assessment is not realistic or feasible, and recommended that CMS consider requiring that States conduct a periodic assessment at least

³⁰ AAC is defined at § 447.502 to mean the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

every 2–3 years to reflect current costs, but not less than 2 years.

Response: We appreciate the commenters' suggestions. CMS is not requiring that a State conduct a cost of dispensing study on an annual basis or any defined period of time. If the State proposes a change to the ingredient cost reimbursement methodology, the State must also review the adequacy of their current professional dispensing fees. While this final rule is not designed to mandate the frequency at which States should update their current professional dispensing fees, we encourage States to undertake a periodic assessment of whether pharmacy dispensing costs have changed, especially if there is a change to the ingredient cost such that the State should consider conducting a cost of dispensing study to comply with Federal regulations.

Comment: A commenter recommended enhanced professional dispensing fees for 340B prescriptions to ensure adequate reimbursement. The commenter specifically requested that CMS encourage States to consider enhanced professional dispensing fees for 340B prescriptions to ensure the adequacy of pharmacy reimbursement for 340B covered entities and contract pharmacies.

Response: We appreciate the recommendation regarding enhanced professional dispensing fees for 340B drugs. States continue to have the ability to propose different professional dispensing fees for CODs, such as for specialty drugs, hemophilia drugs, generics, brand drugs, 340B drugs, etc. CMS will review the proposed rates through the SPA process to ensure that each State's proposed reimbursement methodology meets Federal requirements under sections 1902(a)(30)(A) and 1927 of the Act, and the implementing regulations, specifically at §§ 447.502, 447.512, and 447.518.

Comment: Two commenters disagreed with the proposal to require professional dispensing fees to be based on cost data, as opposed to market-based research, and claimed that these proposals are unnecessary and redundant. One commenter was concerned that CMS' proposed requirements divert the States' limited resources away from other more pressing State Medicaid priorities and that CMS' prohibition on the use of market-based reviews of professional dispensing fees is not accompanied by findings that the States' approach is contributing to unsustainable dispensing fee reimbursement. Another commenter stated that imposing stricter standards for cost information in this

case means that dispensing fees are treated differently than traditional Medicaid services. Conducting surveys or other research on cost-based data will be an added burden on States, and it may be difficult to obtain this information from providers as opposed to market-based research.

Response: We understand the concerns raised by commenters; however, CMS has no reason to believe that the provisions provided in this final rule will divert the States' limited resources away from other more pressing State Medicaid priorities. States are not required to complete their own cost of dispensing study. States can propose their professional dispensing fees based on a neighboring State's survey or other credible survey data, as long as it is adequate and reflects the current pharmacy costs of dispensing a prescription in their State.

CMS is requiring that the professional dispensing fee be based on pharmacy cost data, and not be based on a market-based review. We believe that market-based research is insufficient because it does not reflect actual costs to pharmacies to dispense prescriptions.

Comment: Several commenters provided support for data used to determine professional dispensing fees and ingredient costs and offered suggestions on ways to better understand these costs and accommodate individual States' needs. One commenter agreed that to the extent that a State is conducting a cost of dispensing study, it should be a transparent, comprehensive, and well-designed tool that addresses a pharmacy provider's cost to dispense the drug product to a Medicaid beneficiary. Several commenters expressed support for States to periodically assess if pharmacy reimbursement rates accurately reflect current costs, with suggestions for this assessment to occur every 2 to 3 years.

Response: We agree that a State's cost of dispensing survey should be transparent, comprehensive, and reflective of the pharmacy's actual cost of dispensing. As stated earlier, we are currently not requiring that a State conduct a cost of dispensing survey based on any timeframe, but States must review their current professional dispensing fee whenever they propose to change their reimbursement methodologies to ensure it meets Federal requirements under sections 1902(a)(30)(A) and 1927 of the Act, and the implementing regulations, specifically at §§ 447.502, 447.512, and 447.518.

After consideration of public comments on this provision, we are finalizing as proposed.

L. Federal Financial Participation (FFP): Conditions Relating to Physician-Administered Drugs (§ 447.520)

In the proposed rule, we included a provision that would clarify when States are required to invoice for rebates for PADs that are CODs. As background, we noted that, generally, PADs may satisfy the definition of a COD set forth under section 1927(k)(2) of the Act, subject to the limiting definition at section 1927(k)(3) of the Act, and that manufacturer rebates should be collected on these PADs. We noted that in the past, many PADs were classified by Healthcare Common Procedure Coding System (HCPCS)³¹ codes (commonly referred to as J-codes), which group together different manufacturers of the same drug that have different NDC codes within the same J-code, making it impossible to know which manufacturer supplied the drug in question. We noted that these broad J-codes cannot be used to bill for rebates, as they do not identify the specific PADs NDC. Many providers were submitting only these HCPCS codes to the States, rather than the NDC of the specific PAD, making it difficult if not impossible for the State to bill for rebates.³²

To help address this situation, and to improve a State's ability to identify PADs that may be subject to rebates being invoiced, the Congress enacted section 6002 of the Deficit Reduction Act of 2005 (DRA) adding sections 1927(a)(7) and 1903(i)(10)(C) to the Act to require States to collect and submit certain utilization data on certain PADs as a condition for FFP to be available in payments for these drugs, and to facilitate State collection of manufacturer rebates. More specifically, the DRA provisions required that for payment to be available under section

³¹ HCPCS is a collection of standardized codes that represent medical procedures, supplies, products and services. The codes are used to facilitate the processing of health insurance claims by Medicare and other insurers. HCPCS is divided into two subsystems, Level I and Level II. Level I is comprised of Current Procedural Terminology codes (CPT). Level II HCPCS codes identify products, supplies, and services not included in CPT.

³² In its report titled "Medicaid Rebates for Physician Administered Drugs" (April 2004, OEI-03-02-00660), the Office of Inspector General (OIG) reported that of the 17 States that collected drug manufacturer rebates for physician-administered drugs in 2001, 3 collected rebates on all physician-administered drugs. These three States used NDC codes for billing and the remaining 14 States used HCPC codes. These 14 States cross walked HCPC codes to NDC codes for single-source drugs and collected rebates on these drugs only.

1903(a) of the Act for a COD that is a PAD, States had to provide for the collection and submission of utilization data and coding (such as J-codes and NDCs) for all single source PADs (after January 1, 2006) and multiple source drugs (after January 1, 2008) that are a top 20 high dollar volume PAD that appears on a published list (based on highest dollar volume dispensed under Medicaid identified by the Secretary, after January 1, 2007) in order for FFP to be available under section 1903 of the Act in the case of these drugs, and to assist the States in securing applicable Medicaid rebates for these drugs.

We noted that the list of the top 20 multiple source drugs may be modified year to year to reflect changes in such volume. (See section 1927(a)(7)(B)(i) of the Act.) Also, the statute required that only NDCs be used after January 1, 2007 for billing for all PADs that are single source CODs or the 20 multiple source CODs on the list published by the Secretary, unless the Secretary specified that another alternative coding system be used, or the State obtains a “hardship waiver” under section 1927(a)(7)(D) of the Act. Further, if States are not collecting NDCs and submitting the appropriate utilization data for these drugs consistent with the foregoing requirements, FFP is not available in payments for the CODs at issue. In addition, States would be forgoing available manufacturer rebates for these drugs.

We also noted that the regulations at § 447.520 were established to implement these statutory provisions in the 2007 Medicaid Program; Prescription Drugs; Final Rule, specifying the conditions for FFP for PADs (72 FR 39142). Section 447.520(a) specifies that no FFP is available for PADs if the State has not complied with the foregoing requirements pertaining to submission of codes from its providers that allow it to appropriately bill manufacturers for rebates for PADs. For single source PADs, we noted that the requirement to submit appropriate coding went into effect as of January 1, 2006, and specified under § 447.520(a)(1) that States must require providers to submit claims for single source PADs using HCPCS or NDC codes to secure rebates. We also noted that § 447.520(a)(2) further specified that as of January 1, 2008, a State must require providers to submit claims for single source and the top 20 multiple source PADs identified by the Secretary, using NDCs. As such, under current § 447.520(b), as of January 1, 2007, a State must require providers to submit claims for the top 20 multiple source drugs identified by the Secretary as

having the highest dollar volume using NDC numbers to secure rebates, and § 447.520(c) provided the opportunity for States that require additional time to comply with the requirements of the applicable laws and regulations to apply for an extension to comply with the requirements. We noted that we retained this regulatory language without modification in the 2016 COD final rule. See 81 FR 5322.

In the proposed rule, we included a provision to update the regulatory language at § 447.520 to more specifically and accurately conform with the statutory requirements captured at section 1927(a)(7) of the Act. Specifically, in proposed § 447.520(a)(1) and (2), we outline the conditions under which FFP would be available for States, as related to the NDCs States must require providers to use in order for the State to secure rebates for PADs that are CODs. The proposed language clarified that rebates are only due for PADs that are CODs and specified that data must be submitted by providers in the State in order for States to receive FFP as stated under sections 1927(a)(7)(A) and 1927(a)(7)(B)(i) of the Act and secure applicable rebates. In proposed § 447.520(a)(2), we also proposed that States be required to collect rebates on all multiple source PADs in the manner required under section 1927(a)(7) of the Act, for those 20 identified under section 1927(b)(i) of the Act. We also similarly proposed at § 447.520(b) that after January 1, 2007, a State would have to require providers to submit claims for all COD single source and all multisource PADs using NDC numbers to collect FFP and secure rebates.

We also noted that States need to ensure that their Medicaid managed care plans report required drug utilization data in order for States to invoice manufacturers for rebates for CODs, consistent with § 438.3(s)(2) and (3), which were adopted in the 2016 Medicaid Managed Care final rule.³³ Additionally, we proposed at § 447.520(c) to continue to publish the top 20 list of multiple source PADs on an annual basis, as statutorily required, but also stated our expectation that States would invoice rebates for all multiple source PADs that are CODs, not just those identified on this list. In summary, the proposed regulation would require States to require providers to submit NDCs for all multiple source PADs that are CODs, which would then be subject to

manufacturer rebate invoicing, and not limit such rebate invoicing to those on the top 20 high dollar multiple source drug list subject to the statutory requirements in section 1927(a)(7) of the Act. As technology and systems are currently in place, we noted that this proposed regulation would reduce the administrative burden of monitoring any revisions to the top 20 multiple source PADs and allow States to invoice rebates for these PADs that are CODs.

Since publication of the proposed rule, we have determined that we need to rely upon different statutory authority other than section 1927(d)(7) of the Act for our proposed requirements for multiple source drugs that are not among the 20 identified by CMS under section 1927(a)(7)(b)(i) of the Act and § 447.520(c). This is because the statutory language in section 1927(a)(7)(b)(ii) of the Act conditioning FFP on meeting its requirements, and the NDC code requirements in section 1927(c) of the Act, only apply to the 20 multiple source drugs identified under section 1927(a)(7)(b)(i) of the Act, and not to multiple source drugs not on that list. We accordingly are relying on our authority under section 1902(a)(4) of the Act to specify “methods of administration” that “are found by the Secretary to be necessary for the proper and efficient operation” of the State’s Medicaid State plan as authority for our proposal to extend the multiple source PAD requirements under section 1927(a)(7)(B)(ii) and (C) of the Act that only apply to multiple source PADs identified under section 1927(b)(i) of the Act and § 447.520(c) to other multiple source PADs not so identified. Because requirements under section 1902(a)(4) of the Act are enforced under section 1904 of the Act and regulations at § 430.435, we have revised the regulation text to provide that compliance with requirements in § 447.520 applicable to multiple source PADs not on the list of 20 identified under section 1927(b)(i) of the Act and § 447.520(c) will be enforced under section 1904 of the Act and § 430.435. Finally, because the new requirements that apply to multiple source drugs not identified under section 1927(b)(i) of the Act and § 447.520(c) are not effective until the effective date of this final rule, we have distinguished in the regulation text between these new requirements and those that took effect for the 20 identified multiple source drugs in 2006, 2007 or 2008.

We received several public comments on this proposal. The following is a summary of the comments we received and our responses.

³³ 86 FR 27498, May 6, 2016 (<https://www.govinfo.gov/content/pkg/FR-2016-05-06/pdf/2016-09581.pdf>).

Comment: Several commenters support the revisions to the existing regulatory language regarding the use of NDCs to identify PADs and expanding rebate invoicing beyond the top 20 high-dollar volume list for multiple source drugs. Commenters agree this would increase transparency and allow States to obtain both manufacturer rebates and receive FFP for these CODs. One commenter stated that Medicaid managed care plans are in a position to require physicians to submit NDCs with medical claims for drugs administered in the provider office or an outpatient facility, which is consistent with Medicaid claims submission for medical benefit drugs.

Response: We agree with the commenters that the policies we are adopting in this final rule will allow States to obtain both manufacturer rebates and FFP for reporting and invoicing NDC numbers for all single source and multisource PADs that are CODs administered under both the Medicaid FFS and Medicaid managed care programs. Additionally, since most State Medicaid programs currently require their providers to submit NDC numbers on PAD claims for all CODs that are single source or multiple source drugs, we anticipate the administrative burden to be minimal. We expect that Medicaid managed care plans will continue to review and implement policies that will ensure that prescribers are required to include NDC numbers on all PAD claims.

Comment: One commenter noted that CMS and the Office of the National Coordinator for Health Information Technology (ONC) are moving in opposing directions when it comes to which drug codes to utilize when submitting claims. This commenter stated that the ONC HTI-1 proposed rule discusses the possibility of what they refer to as deprecating support for NDC codes in its certification programs in favor of always requiring the use of RxNorm for medications. Additionally, a commenter stated that if NDCs are required for any drug, they need to be supported by a certified health IT system.

Response: We appreciate the comments about ONC's HTI-1 proposed rule and use of RxNorm for exchanging information on clinical drugs to ensure there is no ambiguity when it comes to identical medications that have different names. We note that NDCs provide package-level information about drugs and are used by healthcare organizations when submitting claims for CODs and the vehicle used for State utilization reporting for rebate purposes. RxNorm does not separately capture

drug manufacturer information and will not meet the needs of the MDRP involving direct manufacturer attribution of CODs, as NDCs are required for rebate purposes. The ONC Health IT Certification program establishes certification criteria for health IT products, which are generally used by health care providers in the provision of care. In the HTI-1 final rule, published on January 9, 2024, ONC finalized adoption of NDCs in 45 CFR 170.207(d)(4) through a cross reference to 45 CFR 162.1002(b)(2) as referenced in 45 CFR 162.1002(c)(1) for the period on and after October 1, 2015 (89 FR 1226). ONC also finalized adoption of the United States Core Data for Interoperability version 3 (USCDI v3), a standardized set of health data classes and constituent data elements, in 45 CFR 170.213 (89 FR 1210). In addition to requiring the use of RxNorm for medications, USCDI v3 added optional support for NDCs. As finalized in the HTI-1 final rule, USCDI version 3 will be the only version of USCDI referenced in certification criteria for health IT under the ONC Health IT Certification Program beginning on January 1, 2026 (89 FR 1211), however, health IT developers may update their products to conform to USCDI version 3 in advance of this compliance date. These actions will support the availability of NDCs within certified health IT products in alignment with finalized policies.

Comment: Several commenters opposed this proposed regulation as it mandates submission of NDCs for all CODs, stating it will considerably intensify the administrative tasks for Medicaid providers. It was stated that this requirement that expands the claims for which NDCs must be reported could strain the already limited resources of 340B covered entities. Another commenter suggested requiring NDCs only for medications that cost above a certain dollar threshold to reduce administrative burden.

Response: We appreciate the concerns stated by the commenters referencing the potential administrative burden to Medicaid providers to submit NDCs for all multiple source PADs that are CODs. However, since most State Medicaid programs currently require their providers to submit NDC numbers on their PAD claims for all CODs that are single source or multiple source drugs, we anticipate the administrative burden caused by this rule to be minimal.

After consideration of public comments on this provision, we are finalizing with the revisions set forth previously in this section.

M. Request for Information on Requiring a Diagnosis on Medicaid Prescriptions

In the proposed rule, we noted that Medicaid COD prescription claims do not currently require a diagnosis as a condition for payment. When reviewing claims without a diagnosis, we noted that it is difficult for the pharmacist or the State to determine whether a drug is indeed being used for a medically accepted indication, and appropriately satisfies the definition of a COD, and therefore, is rebate eligible. We also noted that requiring a diagnosis on a prescription may provide more information to the dispensing pharmacist to enable counseling with a focus on drug-disease interaction, which may improve the beneficiary's overall health.

The proposed rule also noted a 2011 OIG Medicare audit that discovered that without a diagnosis code, it is difficult for Part D sponsors to determine whether a drug claim is medically appropriate.³⁴ OIG stated that without access to diagnosis information, CMS cannot determine the indications for which drugs were used. Although this audit referenced Medicare, the same issue is applicable to Medicaid prescriptions. If States are not aware of the diagnosis for which the medication is being used, they are unable to determine if the drug is being used for a medically accepted indication and cannot determine if they should bill for rebates or if coverage is mandatory. Additionally, an article written by the then Principal Deputy Inspector General (and now current Inspector General) and Chief Medical Officer from OIG advocated for a new mandate that physicians include a diagnosis code with prescriptions.³⁵ In 2011, CMS did not concur with OIG's finding, stating that diagnosis information is not a required data element of pharmacy billing transactions, nor is it generally included on prescriptions.

We also noted in the proposed rule that since many prescriptions are being electronically prescribed, it may make it easier for prescribers to include a diagnosis. Further, we noted several instances in which we believed a diagnosis on a prescription could help States, including implementation of certain Medicaid programs and benefits in which they are eligible for enhanced

³⁴ <https://oig.hhs.gov/reports/all/2011/medicare-atypical-antipsychotic-drug-claims-for-elderly-nursing-home-residents/>.

³⁵ STAT Op-Ed by Christi A. Grimm & Julie K. Taitsman | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services ([hhs.gov](https://www.hhs.gov)) <https://www.statnews.com/2021/03/01/why-drug-prescriptions-should-include-diagnoses/> March, 1 2021.

Federal matching funds, assistance to pharmacists to identify safety issues and ensuring prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and assurance that Medicaid reimbursement is limited to drugs with medically accepted indications.

Given the various perspectives, we assumed there would be many interested parties that would have views on a potential requirement to include a diagnosis on a prescription, including but not limited to patients, prescribers, pharmacists, States, and drug manufacturers. Thus, we specifically solicited comments on this topic, its impact on beneficiaries, providers, States, and Medicaid, and any operational implications. We were particularly interested in understanding the benefits and burdens of such a proposal and sought comments on how to mitigate the impact on beneficiaries and providers, and steps which would be needed by States to successfully implement a Medicaid requirement for diagnoses on prescriptions as a condition of FFP. We also requested comments regarding the potential impact of a policy to require Medicaid diagnoses on prescriptions on payment, health care quality, access to care, and program integrity. In addition, we requested comments on the potential impact of such a policy on beneficiary access to commonly used, medically accepted, compendia supported, off-label uses of CODs.

We received many public comments on this request for information on requiring a diagnosis on Medicaid COD prescription claims. The following is a summary of the comments we received and our response.

Comment: A few commenters provided general support for the requirement of diagnoses on prescriptions; however, the majority of commenters stated their strong

opposition to requiring diagnoses on prescriptions. These arguments focused mostly on administrative burden, potential information technology (IT) issues with delays in care, significant system alterations, stigma, and other complications. Several commenters stated that because of the technical and operational challenges of including a diagnosis on a prescription, it could also lead to manufacturers initiating unnecessary disputes. Furthermore, many commenters opposed the requirement of diagnoses on prescriptions due to possible impact on equitable access to care, including delays and denials in care, added burden to patients, exacerbation of already existing barriers to care, and overall reduction in care access.

Response: We appreciate the comments received in response to the request for information on requiring a diagnosis on Medicaid prescriptions. After careful review and consideration of the public comments received, and due to the overwhelming number of comments that were opposed to this requirement, we are not pursuing this requirement in rulemaking at this time. We will continue to review the feedback we receive from interested parties and may address this issue in future rulemaking if appropriate.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a “collection of information” requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Our May 26, 2023 (88 FR 34238) proposed rule (CMS–2434–P; RIN 0938–AU28) solicited public comment on each of the aforementioned issues for the following sections of the rule that contained collection of information requirements. Comments were received and are summarized and responded to later under sections III.B.1. (Identification and Notification to Manufacturer to Correct Drug Misclassification), III.B.2. (Definitions), III.B.3. (State Plan Requirements, Findings, and Assurances), III.B.4. (Federal Financial Participation (FFP): Conditions Relating to Physician-Administered Drugs), and III.B.6. (Standard Medicaid Managed Care Contract Requirements) of this final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ (BLS’) May 2023 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm#23-0000). In this regard, Table 2 presents BLS’ mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 2—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGES ESTIMATES

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and other indirect costs (\$/hr)	Adjusted hourly wage (\$/hr)
Operations Research Analyst	15–2031	45.96	45.96	91.92

As indicated, we adjusted our hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from

study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding Identification and Notification to Manufacturer To Correct Drug Misclassification (§ 447.509(d)(1) Through (4))

We added new paragraphs (d)(1) through (4) to § 447.509 to add new

requirements relating to the process by which CMS would identify when a misclassification of a drug has occurred in MDRP and subsequently notify the manufacturer of the misclassified drug. A manufacturer's effort to address the misclassification of its CODs is currently approved by OMB under control number 0938–0578 (CMS–367). The active collection considers the time and cost incurred by manufacturers when compiling and reporting, or changing, Medicaid drug product and price information on a monthly, quarterly, and on an as-needed basis. The burden may vary by manufacturer based on the extent to which they misclassify drugs and subsequently need to correct those misclassifications. The extent of the burden may also be impacted based on when the misclassification originally occurred. Since the manufacturer requirements and burden do not require any changes as a result of this rule, we are not making any changes under the aforementioned OMB control number. The manufacturer burden is subject to a regulatory impact analysis which can be found in the Regulatory Impact Analysis section in section IV. of this final rule.

We received numerous public comments on these proposals, but very few, if any, addressed this burden. The following is a summary of the comments we received and our response.

Comment: We received three comments that stated that requiring a manufacturer to correct misclassifications of CODs that occurred more than 10 years ago will be more difficult to address due to the 10-year record retention requirement.

Response: Section 1927 of the Act specifies that rebates can be collected back to the effective date of that section of the Act. Thus, manufacturers must correct misclassifications back to the date of the misclassification so that correct rebates may be paid by the manufacturers on these misclassified drugs. As we note in other sections of this final regulation, manufacturers can make reasonable assumptions regarding their data for any period that extends beyond the 10-year record retention if such records are not available.

After consideration of the public comments, we are finalizing § 447.509(d)(1) through (4) as proposed, with the exception of making a modification to § 447.509(d)(4)(i), to add the following language at the end of that section: “In such case, the manufacturer must certify the applicable correction within 30 calendar days.”

2. ICRs Regarding Definitions (§ 447.502)

To further consider commenters' concerns, we are not finalizing at this time our proposal to add a new paragraph (5) to the definition of manufacturer or § 447.510(h) or our proposal to add a new paragraph to § 447.502 to define vaccine for purposes of the MDRP only.

Consistent with our proposed rule, we do not believe that any of the following new terms or definition modifications and clarifications that are being finalized require any effort or impose burden on any public or private entities: (1) proposal to modify the definition of “covered outpatient drug” (§ 447.502), (2) proposal to define “drug product information” (§ 447.502), (3) proposal to define “market date” (§ 447.502), (4) proposal to modify the definition of “noninnovator multiple source drug” (§ 447.502), and (5) proposal to clarify § 447.509(a)(6) through (9) and (c)(4) with respect to “other drugs”. Consequently, none of the definition changes are subject to the requirements of the PRA.

We received extensive public comments on these proposals; however, only a few address estimates of effort and burden. The following is a summary of the comments we received and our responses.

Comment: Regarding the modification to the definition of COD, several commenters expressed their concerns regarding the lack of visibility that CMS, manufacturers, and States have into payer claims data to understand how drugs and associated services are itemized. One commenter suggested manufacturers would have to hire personnel to procure and assess claims data in order to verify rebate invoices from the State. A few commenters questioned the States' ability to capture necessary data for bundled drugs on payer claims. One commenter noted the proposed definition of COD will serve to generate even more good faith disputes, given the greater challenge posed by generating and providing such claims-level detail in relation to bundled payments, which will result in increases in disputed rebate claims and delayed payments to the States due to this longer validation time.

Response: Manufacturers and States should have current procedures and practices in place regarding how they validate invoices for the purpose of paying claims, and thus billing manufacturers for rebates. We acknowledge that as a result of the clarification to the definition of COD in this rule, States may have to consider

how they instruct providers to bill for certain drugs that are paid for under an all-inclusive rate, such that the State or the Medicaid managed care plan can identify CODs that would be eligible for rebates under inclusive payment models.

Comment: One commenter stated that the proposed changes to § 447.502 would result in a significant burden on the manufacturer and thus are subject to the requirements of the PRA.

Response: The commenter did not describe the nature of the burden in any detail, so we are unable to provide a substantive response.

Comment: Regarding the modification to the definition of COD, one commenter stated collecting NDCs and ingredient cost information and applying such information on Medicaid claims forms is both time-consuming and labor-intensive. CMS should, therefore, refrain from imposing more administrative burdens on providers.

Response: We appreciate the comments regarding the potential burden to providers. Pursuant to their State plans, States have the discretion to choose which reimbursement methodology to employ and what drugs, if any, they will carve out from that methodology and directly reimburse for them. States also dictate the terms of what information is necessary from the provider in order for direct reimbursement to be executed. As of January 1, 2007, § 447.520 has obligated States to require that providers submit NDCs for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary. Additionally, we note that in section II.L of this rule, it is required that States provide for the collection of NDCs for all physician-administered single source drugs and multiple source drugs. However, since most State Medicaid programs currently require their providers to submit NDC numbers on their PAD claims for all CODs that are single source or multiple source drugs, we anticipate the administrative burden caused by this rule to be minimal.³⁶

³⁶ Physician-Administered Drug, Paperwork Reduction Act (PRA)—Identifying Medicaid Payment for Physician Administered Drugs (CMS–10215) OMB CONTROL NUMBER: 0938–1026. At the time the original PRA (November 5, 2007) was approved, collecting and submitting PAD data was a greater burden. At that time, patient records were retained primarily in paper, and claim submissions were made utilizing paper forms. Initial estimates were all made based on the standard of practice in 2007. Since that time, subsequent PRA extensions have been approved; however, these versions did not address improved medical standards of practice with respect to record retention and billing, rule-making requirements relating to including the NDC on the claim so States could bill for rebates (that

Comment: We received a few comments suggesting that the proposed requirement to report drug product information monthly would place an unnecessary burden on both manufacturers and the Agency.

Response: Section 1927(b)(3)(A)(v) of the Act states that manufacturers must report, not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require for each of the manufacturer's CODs. Currently, approved by OMB under control number 0938–0578 (CMS–367), we require that certain drug product information be reported not later than 30 days after the date of entering into a rebate agreement, or, for newly introduced drugs, not later than 30 days after the last day of month during which the new drug is introduced. Such drug product information is not required on a monthly or quarterly basis at this time. Unless future changes are made to the MDRP that require monthly or quarterly reporting of certain drug product information, we will not require repeated reporting.

3. ICRs Related to State Plan Requirements, Findings, and Assurances (§ 447.518)

The burden for submissions relating to § 447.518 is currently approved by OMB under control number 0938–0193 (CMS–179 under attachment 4.19–B pertaining to the: methods and standards used for the payment of certain services, and methods and standards used for establishing payment rates for prescribed drugs). Since § 447.518 of this rule clarifies the data requirements that States must submit to establish the adequacy of both the current ingredient cost and the professional dispensing fee reimbursement, this will not add any new or revised requirements or burden, we are not making any changes under that control number.

The proposed rule had inadvertently identified the package as “CMS–10398 #179”. The correct CMS identification number is “CMS–179” as indicated previously in this section. The control number is correct in both instances.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the use of pharmacy cost data to determine professional dispensing fees and

ingredient costs and offered suggestions on ways to better understand these costs and accommodate individual States' needs. One commenter agreed that to the extent that a State is conducting a cost of dispensing study, it should be a transparent, comprehensive, and well-designed tool that addresses a pharmacy provider's cost to dispense the drug product to a Medicaid beneficiary. Several commenters expressed support for States to periodically assess if pharmacy reimbursement rates accurately reflect current costs, with suggestions for this assessment to occur every 2 to 3 years.

Response: We appreciate the commenters' support. We agree that a State's cost of dispensing survey should be transparent and comprehensive, and the results should reflect the pharmacy's actual cost of dispensing a prescription and the ingredient cost of the drug. The survey must be based on actual pharmacy cost of dispensing data, not market-based data. As stated earlier, we are currently not requiring that a State conduct a cost of dispensing survey based on any timeframe, but States must review their current professional dispensing fee whenever they propose to change their reimbursement methodologies to ensure it meets Federal requirements under sections 1902(a)(30)(A) and 1927 of the Act, and the implementing regulations, specifically at §§ 447.502, 447.512, and 447.518.

After consideration of the public comments, we are finalizing the proposed provisions without change.

4. ICRs Relating to Federal Financial Participation (FFP): Conditions Relating to Physician-Administered Drugs (§ 447.520)

We are updating § 447.520 to make it consistent with section 1927(a)(7) of the Act, and codifying the requirement that States must collect NDC information on all single and multiple source PADs that are CODs for the purposes of invoicing manufacturers for rebates, and ensuring that FFP is available, as appropriate. We are requiring that States must invoice for rebates for all PADs that are CODs. We will continue to publish the top 20 high dollar volume list of multiple source PADs, as statutorily required, to provide a means of prohibiting Federal matching funds, as necessary, if States are not requiring the use of NDC codes, and thus not invoicing for rebates on these drugs. This will be applicable to all States; however, we believe this would cause minimal administrative burden because most States, based on their State Drug Utilization Data (SDUD) reported to CMS, are currently

collecting NDC numbers for all CODs, including all single and multiple source PADs and invoicing manufacturers for rebates as applicable under OMB control number 0938–1026 (CMS–10215). Since the provisions will not add any new or revised requirements or burden, we are not making any changes under that control number.

We received public comments on these proposals. The following is a summary of the comments we received and our response.

Comment: Several commenters opposed this proposed regulation as it mandates submission of NDCs for all CODs, and they stated it considerably intensifies the administrative tasks for Medicaid providers. It was stated that this requirement, previously limited to single source PADs and the top 20 multiple source PADs, could strain the already limited resources of 340B covered entities. Another commenter suggested requiring NDC numbers only for medications that cost above a certain dollar threshold to reduce administrative burden to States.

Response: We appreciate the concerns expressed by the commenters referencing potential administrative burden to State providers to submit NDCs for all single source and multiple source covered outpatient PADs. However, since most State Medicaid programs currently require their providers to submit utilization data through use of NDC numbers for all CODs that are single source or multiple source drugs, including PADs, we anticipate the administrative burden to be minimal.

After consideration of the public comments, we are finalizing the proposed provisions without change.

5. ICRs Regarding Verification Survey of Reported CODs Through Data Collection (§ 447.510)

We proposed at § 447.510(k) a process to survey manufacturers to verify prices and charges for certain CODs by requesting and collecting certain information about such prices and charges for a drug reported to us under section 1927(b)(3)(A) of the Act. The proposed survey instruments would have been submitted to OMB for review if the proposed rule was finalized and the corresponding survey instruments (one for requesting information from States as proposed under § 447.510(k)(3)(ii) and (iii)(A), and another for surveying manufacturers).

Through the proposed rule, we solicited comments to help us develop the manufacturer survey and the State survey and received some suggestions. However, we determined not to finalize

the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic. The estimates included in the proposed rule regarding these survey instruments have been removed from the final rule.

6. ICRs Regarding Standard Medicaid Managed Care Contract Requirements (§ 438.3(s))

The following changes regarding drug cost transparency in Medicaid managed care contracts will be submitted to OMB for approval under control number 0938–1445 (CMS–10855).

We are amending § 438.3(s) to require MCOs, PIHPs, and PAHPs that provide coverage of covered outpatient drugs to assign and exclusively use a unique Medicaid-specific BIN and PCN combination, and group number identifiers on all issued Medicaid managed care enrollee identification cards for pharmacy benefits. It is a standard business practice for the MCOs, PIHPs, and PAHPs to routinely issue enrollee identification cards for pharmacy benefits, even though there is no Federal requirement to issue such cards. The MCOs, PIHPs, and PAHPs routinely for all of their lines of business across the industry, to include commercial/private and public sector programs, such as Medicare and Medicaid. Since we believe that this is a standard business practice that is exempt from the PRA (see 5 CFR 1320.3(b)(2)), we are not setting out such burden for managed care plans to program the new codes onto the cards and to issue such cards under this section of the preamble. The burden, however, is subject to a regulatory impact analysis, which can be found in the Regulatory Impact Analysis section in section IV. of this final rule.

Comment: A few commenters noted the administrative burden of creating potentially thousands of unique BIN, PCN, and group number identifiers instead of the requirement using a BIN and PCN combination. Commenters also expressed concern regarding the administrative burden for assigning each enrollee with a unique BIN, PCN, and group number.

Response: CMS is finalizing the rule to include this recommendation to require a BIN and PCN combination, along with a group number identifier, rather than unique numbers for each component. We agree that it would be administratively burdensome to require unique BINs and unique PCNs, along with a group identifier. The combination approach will achieve the intended result, while minimizing any potential administrative issues.

Comment: One commenter stated that there would be a cost associated with reprinting pharmacy identification cards to meet with new requirement. Another commenter expressed concern regarding the potential operational burden for needing to reissue member ID cards to beneficiaries regarding the new BIN/PCN requirement.

Response: This final rule does not mandate reprinting or re-issuance of enrollee identification cards solely based on when a unique BIN and PCN combination and group number identifier is assigned, but rather re-issuance of cards shall bear the unique identifiers upon routine card issuance. Plans are expected to fulfill these requirements within their standard business practices.

The applicability date for the BIN and PCN combination, and group number identifier provision will be the first rating period for State contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following the effective date of the final rule.

Comment: One commenter stated that pharmacies submitting a 340B identifier on claims involves high administrative burden and financial risk and should be considered a last resort.

Response: Inclusion of accurate submission clarification codes is a standard NCPDP guided practice for pharmacies to include additional information to the processor when submitting a claim. We do not believe the submission of accurate submission clarification codes is a burden outside of the normal current business practices. However, the inclusion of 340B identifiers on claims is outside the scope of this final rule.

Additionally, the provision outlined in § 438.3(s)(8) requires that MCOs,

PIHPs, and PAHPs that provide coverage of covered outpatient drugs that contract with any subcontractor for the delivery or administration of the covered outpatient drug benefit must require the subcontractor to report separately the amounts related to:

(1) The incurred claims described in § 438.8(e)(2), such as reimbursement for the covered outpatient drug, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a covered outpatient drug; and

(2) Administrative costs, fees, and expenses of the subcontractor.

We estimate that the reporting requirements would affect 282 managed care plans and 40 States. We further estimate that it would take an Operations Research Analyst at the State level, 25 hours at \$91.92/hr to revise 282 managed care contracts to require those plans to comply with § 438.3(s)(8). In aggregate, we estimated a one-time burden of 1,000 hours (40 State responses × 25 hr/response) at a cost of \$91,920 (1,000 hr × \$91.92/hr).

For the same contract changes between the managed care plans and the subcontractors (mainly PBMs), we also estimated a one-time private sector burden of 7,050 hours (282 managed care plans × 25 hr/response) at a cost of \$648,036 (7,050 hr × \$91.92/hr).

With respect to the reporting burden, we estimate that for 282 PBMs of those 282 managed care plans to separately report incurred claims expenses described in § 438.8(e)(2) from fees paid for administrative activities will take approximately 2 hours annually to identify these costs separately and report separately to the managed care plans. In aggregate, we estimate an annual burden of 564 hours (282 PBMs × 2 hr/response) at a cost of \$51,842.88 (564 hr × \$91.92/hr).

We did not receive any comments regarding the proposed provisions and burden estimates. We are finalizing them in this rule without change.

C. Summary of Burden Estimates

In Table 3, we present a summary of this rule's collection of information requirements and associated burden estimates.

TABLE 3—SUMMARY OF BURDEN ESTIMATES

Regulatory section(s) under Title 42 of the CFR	OMB Control No. (CMS ID No.)	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost (\$/hr)	Total cost (\$)
§ 438.3(s)(8)	0938–1445 (CMS–10855) ..	40 States	40	25	1,000	91.92	91,920
§ 438.3(s)(8)	0938–1445 (CMS–10855) ..	282 managed care plans	282	25	7,050	91.92	648,036
§ 438.8(s)(8)	0938–1445 (CMS–10855) ..	Subcontractor PBMs of the 282 managed care plans.	282	2	564	91.92	51,842.88

TABLE 3—SUMMARY OF BURDEN ESTIMATES—Continued

Regulatory section(s) under Title 42 of the CFR	OMB Control No. (CMS ID No.)	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost (\$/hr)	Total cost (\$)
Total	322 (40 States + 282 managed care plans).	604	Varies	8,614	91.92	791,798.88

IV. Regulatory Impact Analysis

A. Statement of Need

The intent of this final rule is to implement several new legislative requirements relating to the operation of the MDRP and other program integrity and program administration proposals.

For example, section 6 of MSIAA was signed into law on April 18, 2019. Section 6 of MSIAA amended sections 1903 and 1927 of the Act to grant the Secretary additional authorities needed to address drug misclassification, drug pricing, and product data misreporting by manufacturers for purposes of the MDRP. The final rule includes policies to implement these new statutory authorities, as required.

The regulation also aims to implement a provision in section 9816 of the American Rescue Plan Act of 2021, which amended section 1927(c)(2)(D) of the Act, by inserting a sunset date on the limitation on the maximum rebate amount for single source and innovator multiple source drugs, and other drugs.

We are finalizing several important MDRP program administration and integrity policies such as: implementing a time limitation on manufacturer disputes and audits with States regarding rebates. The final rule also specifies a number of existing policies including: the requirements for State reimbursement for prescribed drugs and the conditions relating to payment of FFP for PADs that are CODs dispensed and paid for under the State plan.

The final rule includes two new requirements for the contracts between States and their Medicaid managed care plans, specifically MCOs, PIHPs, and PAHPs. That is, States would be required to include in their contracts with MCOs, PIHPs, and PAHPs a requirement that each Medicaid enrollee's identification card used for pharmacy benefits would include a unique Medicaid-specific BIN and PCN combination, along with a group number. The applicability date of these unique Medicaid-specific BIN and PCN combinations on the enrollee identification cards will be the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following the effective date of the

final rule. This requirement would assist providers in identifying patients as Medicaid beneficiaries.

In addition, we are finalizing that Medicaid MCO, PIHP, or PAHP (managed care plans) that contract with any subcontractor for the delivery or administration of the covered outpatient drug benefit must require the subcontractor to report separately to the MCO, PIHP, or PAHP incurred claims and administrative costs, fees, and expenses of the subcontractor.

Moreover, we are also finalizing additional program integrity and administration policies, including amending the regulatory definition of noninnovator multiple source drug; adding regulatory definitions of a manufacturer's internal investigation, drug product information, and market data; and modifying the definition of COD. Included was also a provision not directly related to MDRP, that is, a proposed revision to third-party liability regulation resulting from statutory changes in the BBA 2018.

On May 17, 2022, the United States District Court for the District of Columbia vacated and set aside the accumulator provisions within the 2020 final rule. The 2020 final rule required manufacturers to "ensure" the full value of the assistance provided by patient assistance programs is passed on to the consumer, and that the pharmacy, agent, or other AMP or best price eligible entity does not receive any price concession, before excluding such amounts from the determination of best price or AMP. In response to the district court's order, we are withdrawing the changes made to these sections by the 2020 final rule.

We received public comments on these provisions. The following is a summary of the comments we received and our responses.

Comment: One commenter stated the regulatory burden of the rule will stifle innovation.

Response: We do not believe the regulatory burden of the rule will stifle innovation. Rather, we believe our policies as contained in this final rule (including BIN/PCN on cards, drug cost transparency in Medicaid managed care contracts, etc.) will help promote transparency, flexibility, and innovation

in the operation of the Medicaid Drug Rebate Program.

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 entitled "Modernizing Regulatory Review" (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and 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, 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 (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's

priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year).

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant under section 3(f)(1). The Office of Information and Regulatory Affairs has also determined that this final rule meets the criteria set forth in 5 U.S.C. 804(2) (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act).

C. Detailed Economic Analysis

There is a need for greater clarity regarding some of the administrative policies of the MDRP, and this final rule aims to establish regulations to provide guidance to States, manufacturers, and other related parties. This final rule addresses these policy issues after considering the evolution of the pharmaceutical marketplace since the development of the MDRP, and the economic, social, and other factors affecting Medicaid providers and beneficiaries. At the same time, this final rule is mindful of the impact of changes in regulations on affected interested parties, and the degree of compliance issued by the agency. Therefore, for these reasons, we prepared the economic impact estimates utilizing a baseline of "no action," comparing the effect of the proposals against not proposing the rule at all.

If the provisions in the final rule are not implemented, there would be no specific policies in place in the MDRP related to the new legislative requirements in MSIAA, and no clear policies to address drug misclassification and drug product information misreporting by manufacturers. Accordingly, the final rule would address other situations in which manufacturers are paying fewer rebates to States than are supported by the pricing and product data that they are currently reporting to MDP. While we believe that most of the drugs in MDP are appropriately classified, we do not know an exact number of those which may be misclassified. For this reason, a robust analytical framework, with baseline scenarios and benchmarks, could not be conducted.

Additionally, if the provisions are not implemented, there would be no regulatory policies for addressing the

provision in the American Rescue Plan Act to sunset the date on the limitation on the maximum rebate amount paid by manufacturers for single source and innovator multiple source drugs, in addition to drugs other than single source and innovator multiple source drugs.

At this time, program integrity and program administration provisions need to be proposed or specified to address the definitions for: covered outpatient drug (COD); drug product information; internal investigation; market date; and noninnovator multiple source drug. Moreover, currently there is a need to: establish a time limitation on manufacturer rebate disputes and audits with States; refine State requirements for State reimbursement for prescribed drugs; and specify conditions relating to payment for PADs. The reasons and rationales for these provisions were detailed in the preamble section of the proposed rule. The economic impacts of these provisions are detailed later in this section of the final rule.

We solicited comments relating to the issues, benefits, and challenges of requiring a diagnosis be included on Medicaid prescriptions, as well as any current data and estimates that could be used to develop an analytical framework for the proposals in this final rule.

1. Benefits

The provision requiring that subcontractors of Medicaid managed care plans, such as PBMs or pharmacy benefit administrators (PBAs), report specific categories of drug expenditures to their contracted managed care plan will benefit States and Medicaid managed care plans, as it assures a more accurate calculation of plans' MLRs and aids States in development of managed care plan capitation rates, resulting in more accurate Medicaid spending. As indicated in the proposed rule, the shift in policy to eliminate spread pricing in Medicaid managed care pharmacy programs has begun in many States. Therefore, the benefit associated with this final regulation, as we noted in the proposed rule, cannot be quantified at the national level. We do not have data on which States have done this already, that is, eliminated spread pricing, versus States that would need to implement this because of this final rule.

However, we believe that the majority of States do not require their Medicaid managed care plans to include such PBM transparency language in their managed care contracts. For that reason, we do expect that implementation of this provision will result in savings to the Medicaid program, as States will

have a better understanding of their pharmacy program spending and can make any adjustments accordingly. While this provision does not eliminate spread pricing in Medicaid, a March 2020 Congressional Budget Office (CBO) estimate of the Federal proposal³⁷ to require pass through pharmacy pricing finds the spread pricing provision would produce Federal savings of \$929 million over 10 years, which translates to a less than 1 percent decrease in Federal Medicaid prescription drug spending.

In regard to Medicaid Drug Rebates (MDR) and penalties for manufacturer misclassification of drugs, these provisions will implement MSIAA provisions related to misclassification. Finalization of the rule could result in monetary and non-monetary penalties against manufacturers, which are not quantifiable at this time. It could also benefit States if they receive any past rebates that are due to them as a result of a manufacturer's misclassification of drugs.

The majority of drugs are appropriately classified in the Medicaid Drug Programs (MDP) system at this time, but there may be some manufacturers that continue to list their drug as a noninnovator multiple-source drug in MDP, when the drug should be listed as a single-source drug or an innovator multiple source drug. The provision allows us to also pursue penalties against manufacturers that will not correct their misclassification and will also allow us to impose penalties on manufacturers that do not pay the unpaid rebates owed to the States as a result of the misclassification.

Modifying the definition of covered outpatient drug will benefit the manufacturers, States, and CMS. The provision will support the States' ability to collect rebates on drugs administered in certain settings when a drug and its reimbursement amount are separately identified on a claim and payment for the drug is made as direct reimbursement. This will make these therapies more affordable to States and increase beneficiary access to these medications. It will benefit manufacturers by providing clarity on drugs that would satisfy the definition of covered outpatient drug and for which compliance with section 1927 of the Act is required. This benefit is currently not quantifiable because we

³⁷ <https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-Federal-policy-approaches-to-address-medicare-prescription-drug-spending/>
#:~:text=This%20estimate%20is%20based%20in,between%20states%20and%20the%20Federal.

do not know how many drugs this provision will affect.

Finalizing the definition of internal investigation at § 447.502 for purposes of manufacturers making pricing metric revisions, as amended from the proposed definition, will benefit States and manufacturers. It will benefit manufacturers because it will provide a clear definition of what CMS views as an internal investigation for purposes of requesting CMS consideration of recalculation of AMP, best price, and customary prompt pay outside of the 12-quarter rule as permitted under § 447.510. Additionally, defining this term will benefit States because it will deter manufacturers from submitting to CMS a request for a restatement of AMP, best price, and customary prompt pay discounts outside of the 12-quarter timeframe, which could trigger manufacturers seeking to collect overpaid rebates unexpectedly. The benefit of defining internal investigation as part of this final rule is not quantifiable as it is not known how many manufacturers will be deterred from submitting the request to restate outside of the 12-quarter timeframe. However, as noted in the proposed rule, we do not get these requests frequently. We did not receive any comments regarding the impact of the definition of internal investigation at § 447.502.

We proposed to update the definition of manufacturer at § 447.502 and to add a new paragraph (h) in § 447.510 to further specify the responsibilities of a manufacturer. After consideration of public comments, we have opted not to proceed with finalizing the proposed definition of manufacturer at § 447.502 and related changes in § 447.510(h) to further consider commenters' concerns.

The provision to define market date using the date of first sale, rather than the date first available for sale, will benefit some manufacturers, CMS, and States. Manufacturers will not be required to report AMP information until they have actual pricing data based on sales data to report. As a result, there will be decreased reliance by manufacturers to use reasonable assumptions to calculate and report AMP. CMS and States will also benefit because we will now have regulatory support for the longstanding policy of determining the baseline information for a drug based on the date the drug was first sold by any manufacturer. Some manufacturers have been incorrectly interpreting the market date of their drug as the date on which their NDC was first sold or marketed, regardless of any prior manufacturer's marketing or sale of the same drug. That is, some manufacturers believe that they can

reset the baseline information for a drug once they purchase the drug, which is not the case.

States are likely to benefit from the provision to establish a 12-quarter rebate manufacturer dispute, hearing, and audit time limitation in § 447.510(i). While the NDRA addresses rebate disputes, the lack of policy on audit and dispute-initiation timeframes has been interpreted as there being no timeline on initiation of disputes on drug utilization data, unreasonably burdening State rebate programs. With this provision, States will no longer have to look back and research paper claims dating back to as early as 1991, which is the beginning of the MDRP. We estimate the provision will reduce the amount of time it will take States to research disputes on rebate claims since manufacturer disputes, hearing requests, and audits initiated after 12-quarters from the last day of the quarter from the date of State invoice will no longer be considered.

Regarding the regulatory revisions regarding FFP for conditions relating to physician-administered drugs, these provisions will benefit States and the Federal Government. By revising the regulations to be consistent with the statute, States will gain a better understanding of the requirement that they must invoice for all covered outpatient single and multiple source physician-administered drugs. This final rule will help ensure that States will receive FFP for these PADs by requiring the collection of NDC numbers and provide additional rebate collection to increase State and Federal revenue. This benefit is not quantifiable because PAD utilization and costs vary among all State programs, but we believe that most if not all States are already billing for rebates for all PADs.

The provision for inclusion of a BIN/PCN combination, along with a group number identifier, on Medicaid managed care enrollee identification cards will benefit States, the Federal Government, providers, and manufacturers. With the inclusion of Medicaid-specific BIN/PCN combinations and group number identifiers on the pharmacy identification cards issued to the enrollees of MCOs, PIHPs, and PAHPs, pharmacies will be able to identify patients as Medicaid beneficiaries. This will be helpful to all parties to ensure that Medicaid benefits are applied appropriately. This will also help avoid duplicate discounts between Medicaid and the 340B Program, which occurs when a State bills for a Medicaid rebate on a discounted 340B drug, because it will provide notice to the provider that

the claim should be identified as being for a 340B drug. This benefit is not quantifiable because it is currently unknown how often patients are not identified as Medicaid beneficiaries.

The provision for drug cost transparency in Medicaid managed care contracts will benefit States and the Federal Government. It will assist Medicaid managed care plans in complying with Federal regulations regarding MLRs and guidance by effectively requiring subcontractors to appropriately identify and classify certain costs, so that the managed care plan can appropriately calculate their MLR.

In particular, managed care plans that provide coverage of CODs must require the subcontractor to report separately the amounts related to the incurred claims described in § 438.8(e)(2) (such as reimbursement for the covered outpatient drug, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a covered outpatient drug) from administrative costs, fees and expenses of the subcontractor. By receiving reports that separately identify fees that are outside of the prescription and dispensing fee costs of a drug, the MCO, PIHP, or PAHP will be able to calculate and report its MLR more accurately.

MLR calculations are used to develop capitation rates paid to Medicaid managed care plans; thus, their accuracy is critical in assuring that Medicaid payments are reasonable and appropriate. Managed care capitation rates must (1) be developed such that the plan will reasonably achieve an 85 percent MLR (§ 438.4(b)(9)) and (2) be developed using past MLR information for the plan (§ 438.5(b)(5)). In addition to other standards outlined in §§ 438.4 through 438.7, these requirements for capitation rates related to the MLR are key to ensuring that Medicaid managed care capitation rates are actuarially sound. In addition, Medicaid managed care plans may need to pay remittances to States should they not achieve the specific MLR target when a remittance is required by a State. Thus, the accuracy of MLR calculation is important to conserving Medicaid funds.

The payment of claims provision will benefit States, the Federal Government, providers, and beneficiaries. This provision will benefit both the Federal Government and States as it corrects omissions in regulatory language to align with statutory language, permitting Medicaid to remain the payer of last resort. These revisions will also benefit beneficiaries and providers as

they permit States to pay claims sooner than the specified waiting period, when doing so is cost-effective and necessary to ensure access to care.

The proposal to clarify our longstanding policy to account for manufacturer stacking of discounts when determining best price is not being finalized at this time. Therefore, we will not be responding to any comments submitted on the impact of this specific proposal.

2. Costs

a. Manufacturer Misclassification of a Covered Outpatient Drug and Recovery of Unpaid Rebate Amounts Due to the Misclassification and Other Penalties

In regard to the costs associated with this provision, if CMS identifies that a drug has been misclassified, the manufacturer will be responsible for paying any unpaid rebates to the States as a result of the misclassification. This will mean that the manufacturers will have to determine which prices to use to calculate the past due rebates and for which unit rebates are owed, and then pay the States the calculated rebate amount. They will also have to report to CMS that such rebates have been paid. In this situation, the States will not incur any new costs; rather it will help ensure that manufacturers are accurately paying rebates to States, thus benefitting the States. In some cases, the States may have to pay rebates back to the manufacturer if the manufacturer's misclassification resulted in overpayment of rebates to the States. In this situation, the States would incur costs as they reimburse the manufacturer for the overpayment. CMS may be required to share in repayment of some of these rebates.

The amount of rebates owed or collected by the manufacturers under these new regulatory misclassification provisions cannot be estimated. We cannot predict how many, if any, drugs are or will be misclassified and require payment of unpaid rebates.

We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

b. Suspension of Manufacturer NDRA for Late Reporting of Pricing and Drug Product Information

This provision will implement existing statute and is being implemented to encourage manufacturer adherence with program reporting requirements and enhance administrative efficiency. Manufacturers that are not reporting their pricing or product information in a timely manner

per statutory and regulatory requirements will have their rebate agreement (and those of their associated labelers) suspended for purposes of Medicaid and the MDRP. This means that States will not have to cover or pay for the drugs of the manufacturer during the period of the suspension unless they are paid through their own State funds. Lack of timely reporting by manufacturers can also reduce rebates that are owed to States by a manufacturer and can affect the number of multiple source drugs for which Federal Upper Limits (FULs) can be established. Thus, this suspension authority will serve as an incentive for manufacturers to report their product and pricing information timely so that drugs of the manufacturer will continue to be covered under Medicaid and the MDRP.

This provision will have minimal cost to the States as their only responsibility will be to notify prescribers and patients that a drug is not available under the MDRP for the period of the suspension. Similar to §§ 431.211 and 435.917, we required that States notify beneficiaries at least 30 days before a drug is no longer available because of a suspension of a manufacturer's drug rebate agreement. Since States may choose their preferred method of notification of beneficiaries, including through email, form letters, list serves, or Medicaid portals, we solicited comments on how to develop a cost estimate.

We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

c. Modified the Definition of Covered Outpatient Drug

This provision may increase manufacturers' rebate liability to the States because it will clarify those CODs that could be billed for rebates. At this time, we cannot determine an estimate of burden for manufacturers regarding this item because we do not have an estimate of the number of drugs that could potentially be billed for rebates as a result of this clarification. States only have to report utilization of drugs for which rebates are invoiced. If States were not invoicing for rebates for certain types of claims previously, we do not have quantifiable information about the additional rebates that may be now collected. Additionally, States may need to educate their providers on billing procedures. We believe this will involve minimal burden, as States could inform their providers as part of their regular communications.

We received public comments on these Regulatory Impact Analysis

provisions. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that CMS should undertake a formal regulatory impact analysis regarding the modification to the definition of covered outpatient drug to properly assess positive and negative effects.

Response: As we stated in the proposed rule, we are unable to quantify what impact the modification to the definition of covered outpatient drug will have. However, this will clarify for States and manufacturers the application of the "direct reimbursement" part of the definition of COD and may assist in identifying utilization that qualifies for rebates in situations where States have not previously collected rebates. We accounted for the administrative costs of reviewing and interpreting this definition in the Regulatory Review section later in this rule.

Comment: One commenter pointed out implementation challenges, including substantial changes to billing and claims systems to capture information about the specific services that are included in a bundled payment. They stated it would be extremely difficult to understand all of the scenarios where the payment for a code was inclusive of the drug reimbursement.

Response: We intend for the modification to the definition to provide clarification regarding when a payment represents direct reimbursement for a drug. Based on the comments, though, it is evident that our proposed modification to the definition did not make this clear. In the past we have stated that no rebate liability attaches to drugs that are paid for as part of bundled payments. However, we have received questions from interested parties to define situations in which rebates can be billed for drugs that are part of inclusive payments in which the quantity of drug dispensed or administered can be identified. We are therefore modifying the proposed definition of direct reimbursement to make it clear that, for such rebates to be billed, the inclusive payment includes an amount directly attributable to the drug, where such amount is based on a reimbursement methodology that is included in the applicable section of the State plan. We believe that the modification to the proposed definition resolves the implementation concerns.

After consideration of public comments, we are finalizing the provision with the amended language as set out at the end of this document.

d. Defined Internal Investigation for Purposes of Pricing Metric Revisions

The cost of the final definition will be the amount of time that needs to be taken by manufacturer personnel to determine how to apply the definition of internal investigation when considering submitting a request to CMS for a recalculation. This legal analysis will not apply to every manufacturer or to every drug of the manufacturer. It will only apply if the manufacturer wants to submit a request for CMS to consider recalculation outside of 12 quarters for one or more of its CODs. As stated in the proposed rule, we have received only a minimal number of such requests from manufacturers. We assumed the time to perform legal analysis is 5 hours. Using the May 2023 mean (average) wage information from the BLS for lawyers (Code 23–1011), we estimated that the cost of reviewing this provision is \$169.68 per hour, including fringe benefits and other indirect costs (<https://www.bls.gov/oes/current/oes231011.htm>) with a total cost of $(\$169.68 \times 5)$, is \$848.40 for each manufacturer. We estimated that only one percent of manufacturers will submit a request for a recalculation annually outside of the 12-quarters. One percent of 792 manufacturers is approximately 8 manufacturers, with a total one-time cost of \$6,787.20 $(8 \times \$848.40)$. We estimated one percent because currently only one manufacturer has submitted such a request. This provision will not impose substantial costs on the State.

We received no public comments on these estimates associated with the definition of internal investigation. We are adopting a definition of internal investigation at § 447.502, as amended and discussed in section II.C.1.c. of this final rule.

e. Revised Definition of Manufacturer for NDRA Compliance

Several analyses and reviews were performed to better assess current manufacturer compliance with the requirement that a manufacturer have a rebate agreement in effect that includes all associated labeler codes. While this policy has already been specified in guidance and preambles, we are opting not to finalize the proposed definition of manufacturer and conforming changes in § 447.510 at this time to further consider commenters' concerns.

f. Define Market Date

In regard to costs associated with defining market date, if manufacturers have not provided CMS with accurate market dates, they may need to develop

a methodology to determine the accurate dates. That is because they may have assumed that the market date of the COD is the date that they purchased it, rather than the date the COD was sold by any manufacturer and may not have access to relevant pricing records before the date they purchased the drug. In addition, going forward, manufacturers will have to identify when their first sales of the COD occur to accurately identify the market date of the COD. At this time, we cannot determine cost estimates associated for this provision. This provision will not impose substantial costs on States.

We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

g. Modify the Definition of Noninnovator Multiple Source Drug

This provision proposed a technical correction to the regulatory text to conform the language in the definition of an N drug to the language in the definition of an I drug. We do not anticipate any impact on interested parties.

We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

h. Define Vaccine for Purposes of the MDRP Only

We are opting not to finalize the proposed definition of vaccine at this time. We are continuing to review the input provided by commenters on the proposed definition, which may be used in future rule making on this topic.

i. Proposal To Establish a 12-Quarter Rebate Audit Time Limitation

We estimated a decrease in burden associated with this proposal. After contacting several States, we estimated that per State, between 10 and 80 disputes are initiated routinely in a quarter on rebate claims greater than 3 years old, and those disputes on average take an Operations Research Analyst between 30 minutes and 4 months to resolve, depending on the complexity of the dispute and how long ago the claim was paid. That means at any given time, the States, many of which have limited staff resources in the pharmacy program, are dealing with hundreds of manufacturer disputes for rebate claims that are more than 3 years old. For our best estimate of the quantifiable impact, with all 50 States, the District of Columbia, and Puerto Rico being affected, we estimated it would take 52 Operations Research Analysts, 15–2031 (1 for each State) 7 hours to resolve a

dispute at \$91.92/hr (<https://www.bls.gov/oes/current/oes152031.htm>) \$643.44 $(\$91.92 \times 7)$ (for 45 outstanding disputes $[(10 \text{ disputes} + 80 \text{ disputes})/2]$ per State for claims greater than 3 years old. We, therefore, estimated a one-time decreased burden reduction of \$6,022,598.40 $(45 \text{ disputes} \times \$643.44 \text{ hr/dispute} \times 52 \text{ States} \times 4 \text{ quarters (1 year)})$. Manufacturers will only have the ability to initiate a dispute on claims for up to 12 quarters, from the last day of the quarter from the date of State invoice postmark.

We did not receive public comments relating to regulatory impact on this provision, and we are finalizing as proposed.

j. Proposals Related to State Plan Requirements, Findings, and Assurances

The clarification is necessary so payments to pharmacy providers are consistent with efficiency, economy, and quality of care, and are sufficient to provide access to care and services at least equivalent to the care and service available to the general population. Pharmacists must be accurately reimbursed by the State for drug ingredient costs and professional dispensing services under § 447.518.

We have not included time and cost burdens for individual State dispensing fee surveys in this final rule because we cannot accurately determine whether a State would choose to conduct a State-specific cost of dispensing survey or use another State's survey. As such, this is an unquantifiable cost to States and therefore, we have not included an estimate. States have several options when reviewing and adjusting their professional dispensing fee (including using a neighboring State's survey results, conducting their own survey, or using survey data from a prior survey).

In the proposed rule, we specified that the type of data that States must submit to justify their professional dispensing fees must be based on actual costs of dispensing.

We received public comments on this Regulatory Impact Analysis provision. The following is a summary of the comments we received and our responses.

Comment: Two commenters disagreed with the proposal to require professional dispensing fees to be based on cost data, as opposed to market-based research, and claimed that these proposals are unnecessary and redundant. One commenter was concerned that CMS' proposed requirements divert the States' limited resources away from other more

pressing State Medicaid priorities and that CMS' prohibition on the use of market-based reviews of PDFs is not accompanied by findings that the States' approach is contributing to unsustainable dispensing fee reimbursement. Another commenter stated that imposing stricter standards for cost information in this case means that dispensing fees are treated differently than traditional Medicaid services. Conducting surveys or other research on cost-based data will be an added burden on States, and it may be difficult to obtain this information from providers as opposed to market-based research.

Response: We understand the concerns; however, CMS has no reason to believe that the provisions provided in this final rule will divert the States' limited resources away from other more pressing State Medicaid priorities. States are not required to complete their own cost of dispensing study. States can propose their professional dispensing fees based on a neighboring State's survey, or other credible survey data, as long as it is adequate and reflects the current pharmacy costs of dispensing a prescription in their State.

CMS is also requiring that the professional dispensing fee be based on pharmacy cost data, and not be based on a market-based review, since we believe that market-based research is insufficient because it does not reflect actual costs to pharmacies to dispense prescriptions.

After consideration of public comments on this provision, we are finalizing as proposed.

k. Federal Financial Participation: Conditions Relating to Physician-Administered Drugs

All States currently have an existing process in place to collect and invoice for covered outpatient single source and the top 20 high volume multiple source physician-administered drugs in accordance with regulatory language in § 447.520, which may limit the additional burden associated with collecting and invoicing NDC information for all covered outpatient single and multiple source PADs.

It is difficult to quantify a specific dollar value for the expected revenue increase at this time. PAD utilization and costs vary among all State programs; however, once implemented, and all States are collecting rebates for all single and multiple source COD PADs, a baseline can be established. All States currently have this process well established under regulatory language in § 447.520.

These provisions clarify the existing statute to ensure FFP and rebate collection for all covered outpatient single and multiple source physician-administered drugs.

We received public comments on this Regulatory Impact Analysis provision. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed this proposed regulation which mandates submission of NDCs for all covered outpatient drugs, as it considerably intensifies the administrative tasks for Medicaid providers. It was stated that this requirement, previously limited to single source PADs and the top 20 multiple source PADs, could strain the already limited resources of 340B covered entities. Another commenter suggested requiring NDC numbers only for medications that cost above a certain dollar threshold to reduce administrative burden.

Response: We appreciate the concerns expressed by the commenters referencing potential administrative burden to State providers to submit NDC numbers for all single source and multiple source drugs. However, since most State Medicaid programs currently require their providers to submit utilization data through use of NDC numbers for all CODs that are single source or multiple source drugs, we anticipate administrative burden to be minimal. Additionally, this benefit is not quantifiable because PAD utilization and costs vary among all State programs, but we believe that most if not all States are already billing for rebates for all PADs.

After consideration of public comments on this Regulatory Impact Analysis provision, we are finalizing as proposed.

l. BIN/PCN on Medicaid Managed Care Cards

The cost is limited to the time the Medicaid managed care plans need to program the new codes onto the cards.

We did not receive public comments on this Regulatory Impact Analysis provision regarding the programming time it would take for managed care plans to assign the newly required BIN and PCN combination, and group number identifiers onto the enrollee identification cards, and therefore, we are finalizing as proposed.

m. Drug Cost Transparency in Medicaid Managed Care Contracts

The costs associated with this change is the cost to managed care plans and their subcontractors to negotiate and

revise contracts to ensure administrative fees are separately identifiable from reimbursement for CODs, dispensing fee costs and other patient costs that need to be captured as incurred claims under § 483.8(e)(2). As discussed in the section III. of the proposed rule, we estimated that these requirements would affect 282 managed care plans and their subcontractors (mainly PBMs) in the country and 40 States. We estimated it would take an Operations Research Analyst (Code 15–2031) 25 hours at \$91.92 per hour, including fringe benefits and other indirect costs, to renegotiate and revise 282 Medicaid managed care contracts to require the MCO, PIHP, or PAHP to require its subcontractors to separately report information on incurred costs (as described in § 438.8(e)(2)) and fees paid to the subcontractor for administrative services. We, therefore, estimated that the burden associated with this provision will be a one-time cost for each managed care plan of \$2,298 or \$648,036 for all managed care plans. There are 40 States with Medicaid managed care plans; therefore, we estimated the State's Operations Research Analyst (Code 15–2031) 25 hours at \$91.92 per hour, including fringe benefits and other indirect costs to revise State contracts for a one-time cost per State of \$2,298 or \$91,920 for all 40 States.

Federal savings may be captured by an estimate associated with a statutory change to eliminate PBM spread pricing at \$929 Million over 10 years.³⁸ A March 2020 CBO *estimate* for the Federal proposal to require pass through pricing finds the spread pricing provision would produce Federal savings of \$929 million over 10 years, which translates to a less than 1 percent drop in Federal Medicaid prescription drug spending. It is unclear what analysis or assumptions went into these estimates, but they are highly dependent on assumptions or understanding of the extent to which spread pricing currently exists in Medicaid.

There is currently no Federal prohibition on using spread pricing in Medicaid. As noted, we issued guidance in 2019 regarding the impact of the lack of transparency between costs for administrative functions versus actual costs for Medicaid-covered benefits on the managed care plan's MLR calculation. The 2019 CIB is clear that when the subcontractor, in this case the PBM, is performing administrative

³⁸ <https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-Federal-policy-approaches-to-address-medicare-prescription-drug-spending/>
#:~:text=This%20estimate%20is%20based%20in,between%20states%20and%20the%20Federal.

functions such as eligibility and coverage verification, claims processing, utilization review, or network development, the expenditures and profits on these functions are a non-claims administrative expense as described in § 438.8(e)(2)(v)(A), and should not be counted as an incurred claim for the purposes of MLR calculations.

If a subcontractor incorrectly categorizes these administrative fees as incurred claims under § 438.8(e)(2), it increases the MLR numerator. By requiring managed care plans to require subcontractors to separately report their administrative fees (that is, separately identified from incurred claims such as reimbursement for covered outpatient drugs, dispensing fees, and other patient services), the managed care plan is better able to ensure the accuracy of MLR as well as the base data utilized when developing capitation rates for Medicaid managed care plans, and accurately reflects only medical expenditures, thus generating savings to the Medicaid program. For those States that may not already have this requirement as part of its contract with the managed care plan, this provision would be a cost to the State to revise managed care plan contracts. It provides transparency to the State and the managed care plan as to which subcontractor costs are incurred claims under § 438.8(e)(2) (costs of CODs and dispensing fees) versus administrative fees.

We received the following comment regarding this Regulatory Impact Analysis provision.

Comment: A commenter specified that the proposed rule aiming to enhance transparency in PBM reporting may unintentionally raise costs for the Medicaid program due to PBMs acting as middlemen. Moreover, shifting away from spread pricing contracts, often without added fees, could lead to higher-cost fee-based contracts despite their increased transparency, ultimately imposing a higher cost on payers.

Response: We do not agree that the provision in § 438.3(s)(8) that requires the managed care plan to specify in its contract with subcontractors that the subcontractor is required to report separately the amounts related to incurred claims and administrative costs, fees and expenses of the subcontractor will unintentionally raise costs for the Medicaid program. We believe this information will help to inform the State's decision-making relating to the administration of the prescription drug benefit. It will also help the Medicaid managed care plans have more accurate data to calculate

their MLRs, as well as ensure that States can accurately develop capitation rates. Finally, it will help States and managed care plans ensure that PBMs specifically are being appropriately compensated for their services by requiring that the subcontractors report separately incurred claims for CODs and administrative fees, costs, and expenses in sufficient detail and the level of detail must be no less than the reporting requirements in § 438.8(k).

After consideration of public comments on this provision, we are finalizing § 438.3(s) with some changes to the proposed regulatory text. We will modify § 438.3(s)(8) by: adding at the beginning of paragraph (8) the phrase "The MCO, PIHP, or PAHP" to conform with the other paragraphs in § 438.3(s), inserting "must" to replace "to" for additional clarity, and inserting "to the MCO, PIHP, or PAHP" for clarity on the entity that the subcontractor reports the required information to. We also are adding § 438.3(w) to include an applicability date for the requirements of paragraphs (s)(7) and (s)(8), which will be the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year following November 19, 2024.

n. Proposals Related to Amendments Made by the American Rescue Act of 2021—Removal of Manufacturer Rebate Cap (100 Percent AMP)

This provision is a direct result of a statutory change to remove the cap on Medicaid drug rebates (the maximum rebate amount). Medicaid savings would be generated by the increased rebates due to the removal of the cap on rebates with an estimate of an average of \$14.21 billion over 10 years.³⁹ By removing the cap on the amount manufacturers would be required to pay for Medicaid drug rebates, Medicaid rebate revenue would increase thus producing savings to the Federal government (Table 5 includes the savings which are CBO estimates from when the statute was amended). The costs associated with this requirement are to manufacturers. Manufacturers would also need to make minor changes to their systems to address the removal of the cap. As stated in the proposed rule, States would realize some savings because of the increase in rebates; however, it is not known if manufacturer drug prices to Medicaid would decrease because of the removal of the cap as manufacturers

adjust pricing to reflect the increase in Medicaid drug rebates.

We did not receive public comments on the estimates related to this Regulatory Impact Analysis provision and are finalizing as proposed.

o. Payment of Claims

At this time, there is no need to determine cost estimates for this item. The 2020 final rule revised the regulations and captured cost estimations and collection of information. This revision would add omitted statutory language to the existing regulation. This change would not produce new burden not already captured in the final rule Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements.

We received 2 public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters stated they were in support of our proposal to correct omissions in regulatory language to align with statutory language, ensuring Medicaid remains the payer of last resort while also permitting States to pay claims sooner than the specified waiting periods when doing so is cost-effective and necessary to ensure access to care.

Response: We appreciate the support for this proposal.

After consideration of public comments, we are finalizing this provision as proposed.

p. Requests for Information on Requiring a Diagnosis on Medicaid Prescriptions

This provision was a request for information only. We sought comments on how to negate any foreseeable impact on beneficiaries and providers and steps which would be needed by States to successfully implement a Medicaid requirement for diagnosis on prescriptions.

We received many public comments on these proposals. The following is a summary of the comments we received and our response.

Comment: A few commenters provided general support for the requirement of diagnoses on prescriptions; however, the majority of commenters stated their opposition to requiring diagnoses on prescriptions. These arguments focused mostly on administrative burden, potential

³⁹ <https://www.macpac.gov/wp-content/uploads/2019/06/Next-Steps-in-Improving-Medicaid-Prescription-Drug-Policy.pdf>.

information technology (IT) issues with delays in care, significant system alterations, stigma, and other complications. Several commenters stated that because of the technical and operational challenges of including a diagnosis on a prescription, it could also lead to manufacturers initiating unnecessary disputes. Furthermore, many commenters opposed the requirement of diagnoses on prescriptions due to possible impact on equitable access to care, including delays and denials in care, added burden to patients, exacerbation of existing barriers to care, and overall reduction in care access.

Response: We appreciate all the comments received for the request for information on requiring a diagnosis on Medicaid prescriptions.

After careful review and consideration of the public comments received, and due to the overwhelming number of comments that were opposed to this requirement, we are not going to pursue this requirement in rulemaking at this time. We will continue to review the feedback we receive from interested parties and may address this provision in future rulemaking if appropriate.

q. Proposal To Account for Stacking When Determining Best Price

We are opting not to finalize the proposed provision related to stacking when determining the best price at this time to further consider comments received and pursue collection of information through a separate Paperwork Reduction Act (PRA) request to collect additional information related to manufacturers' stacking methodologies.

r. Proposal Regarding Drug Price Verification Through Data Collection

We are opting not to finalize the proposed provision related to the drug price verification survey at this time.

s. Proposal To Rescind Revisions Made by the December 31, 2020 Final Rule To Determination of Best Price (§ 447.505) and Determination of Average Manufacturer Price (AMP) (§ 447.504) Consistent With Court Order

In the 2020 final rule, CMS revised the various patient assistance program exclusions from AMP and best price at §§ 447.504(c)(25) through (29) and (e)(13) through (17) and 447.505(c)(8) through (12) to add language that would require manufacturers "to ensure" the assistance provided by these patient assistance programs is passed on to the consumer, and the pharmacy, agent, or other AMP or best price eligible entity does not receive any part of the

manufacturer patient assistance in the form of additional price concessions.

As part of the 2020 final rule, the impact analysis for the exclusions to ensure such patient assistance is passed on to the patient is discussed at length (see 85 FR 87098 through 87100). We concluded at that time that based upon the studies noted in the analysis, the value of patient assistance programs is being eroded by PBM copay accumulator programs because the patient assistance is accumulating to the economic benefit of health plans, not to patients, given that the health plans' spending on drugs for patients decreases as a result of such programs. We also believed that, even with the changes in the rule, that manufacturers would continue to offer patient assistance because the infrastructure was there to ensure, in accordance with the regulation, the patient assistance accrued to the patient, rather than the plan. Therefore, we believed that patients would not be significantly impacted by the modifications that the manufacturers may have needed to make to ensure the pass through of the patient assistance to the patient consistent with section 1927 of the Act.

In May 2021, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a complaint against the Secretary requesting that the court vacate these amendments to § 447.505(c)(8) through (11) (85 FR 87102 and 87103), as set forth in the 2020 final rule. On May 17, 2022, the United States District Court for the District of Columbia ruled in favor of the plaintiff and ordered that the applicable provisions of the 2020 final rule be vacated and set aside.

In response to the order issued by the United States District Court for the District of Columbia to vacate the applicable provisions of the 2020 final rule, we proposed to withdraw the applicable changes made to § 447.505, and, for consistency, withdraw the corresponding revisions to regulations addressing AMP made by the 2020 final rule. At the time of the 2020 final rule, we could not quantify to what degree the changes would impact manufacturers or patients. Therefore, we cannot quantify the impact on manufacturers and patients because of the rescinding of this rule.

3. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret the proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of

entities that will be directly impacted and will review the proposed rule, we assume that the total number of unique commenters is based on the current 792 manufacturers participating in the MDRP. Nevertheless, we estimated that the current 792 manufacturers would need to review the proposed rule.

Furthermore, we anticipated one medical and health service manager (Code 11–9111) from each of the 50 States, the District of Columbia, and Puerto Rico that cover prescription drugs under the MDRP, will review the proposed rule. Additionally, we estimated that 19 trade organizations may review the proposed rule. The estimate of trade organizations is based on a previous rule pertaining to the MDRP, in which 19 formal comments were received from trade organizations. It is possible that not all commenters or drug manufacturers will review the proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. In addition, we assumed that some entities will read summaries from trade newsletters, trade associations, and trade law firms within the normal course of keeping up with current news, incurring no additional cost. Therefore, we assumed that approximately 863 (792 manufacturers + 52 States + 19 trade associations) entities may review the proposed rule. For these reasons, we believed that the number of commenters would be a fair estimate of the number of reviewers who are directly impacted by the proposed rule. We solicited comments on this assumption.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule. However, for the purposes of our estimate, we assumed that each reviewer reads 100 percent of the proposed rule.

Using the May 2023 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing the proposed rule is \$129.28 per hour, including fringe benefits and other indirect costs (<https://www.bls.gov/oes/current/oes119111.htm>). Assuming an average reading speed of 250 words per minute, we estimated that it would take approximately 288 minutes (4.8 hours) for the staff to read the rule, which is approximately 72,000 words. For each medical and health service manager (Code 11–9111) that reviews the proposed rule, the estimated cost is $(4.8 \times \$129.28)$ or \$620.54. In part, we estimated that the cost of reviewing this final rule by medical and health service managers is \$535,526.02 $(\$620.54 \times 863)$

reviewers). Additionally, there is also a lawyer who will review the final rule. Using the May 2023 mean (average) wage information from the BLS for lawyers (Code 23–1011), we estimated that the cost of reviewing the final rule is \$169.68 per hour, including fringe benefits and other indirect costs (<https://www.bls.gov/oes/current/oes231011.htm>). Assuming an average reading speed of 250 words per minute,

we estimated that it would take approximately 288 minutes (4.8 hours) for the staff to review the final rule, which is approximately 72,000 words. For each lawyer (Code 23–1011) that reviews the proposed rule, the estimated cost is (4.8 × \$169.68) or \$814.46. In part, we estimated that the cost of reviewing the rule by lawyers is \$702,878.98 (\$814.46 × 863 lawyers). In total, we estimated the one-time cost of

reviewing the rule is \$1,238,405.00 (\$535,526.02 + \$702,878.98). We acknowledged that these assumptions may understate or overstate the costs of reviewing the rule. We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

TABLE 4—SUMMARY OF THE ONE-TIME QUANTITATIVE COSTS AND BENEFITS

Line item	Cost	Entity	Timeframe
Regulatory review	\$1,238,405.00	Manufacturers, States, Trade Association.	One-time cost.
Define manufacturer internal investigation	6,787.20	Manufacturers	One-time cost.
Establish a 12-Quarter Rebate Audit Time Limitation	(6,022,598.40)	States and Federal Government	One-time cost savings.
Drug Cost Transparency in Medicaid Managed Care Contracts	648,036.00	Managed care plans and their subcontractors.	One-time cost.
Drug Cost Transparency in Medicaid Managed Care Contracts	91,920	States	One-time cost.
Total	(4,037,450.20)		

TABLE 5—SUMMARY OF THE ANNUAL QUANTITATIVE COSTS AND BENEFIT

Line item	Cost	Entity	Timeframe
Drug cost transparency in Medicaid managed care contracts	(\$929,000,000.00)	Federal Government	Over 10 years.
Removal of manufacturer rebate cap (100% of AMP)	(14,211,000,000.00)	Federal and State Governments	Over 10 years.
Total	(15,140,000,000.00)		

D. Alternatives Considered

Some provisions are directly linked to statute and therefore alternatives cannot be considered. Nevertheless, alternatives which we have considered are detailed in this section.

We proposed to modify the definition of manufacturer for purposes of satisfying the requirement at section 1927(a)(1) of the Act which requires a manufacturer to have entered into and have in effect a NDRA. However, based on public comment, we are not finalizing this proposal at this time.

We proposed to define vaccine to endeavor to prevent disputes with manufacturers about what products are and are not vaccines for purposes of the MDRP, given that there may be products coming to market for which this definition might help provide clarity. However, we are not finalizing this proposal at this time. We are continuing to review the input provided by

commenters on the proposed definition, which may be used in future rule making on this topic.

We proposed to specify the time limitation on manufacturers initiating disputes, hearings, or audits with States. While the NDRA addresses dispute resolution, it provides no guidance on whether a timeline applies to the initiation of such disputes, hearings, or audits. There have been reports from States of new disputes being initiated on claims dating back several decades to paper claims, which is placing unnecessary burden on many State rebate programs. Implementation of this provision is necessary to ensure administrative efficiency. An alternative considered was to not clarify this provision; however, this alternative would have allowed disputes to be initiated on claims for any time period, causing undue strain, work hours, and costs on rebate programs, which directly counters the purpose of the program to

offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid patients. Additionally, we believe the more recent the claim corresponding with the dispute, the easier it will be to resolve disputes, and this provision will improve the accuracy and speed of dispute resolutions.

We did not receive public comment on this proposal, which relates to our regulatory impact analysis, and we are finalizing this provision.

E. 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 6 showing the classification of the impact associated with the provisions of this final rule.

TABLE 6—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS/SAVINGS

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs/Savings:				
Annualized Monetized (\$million/year)	(\$0.54) (0.46)	2021 2021	7 3	2024–2034 2024–2034

TABLE 6—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS/SAVINGS—Continued

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs/Savings:				
Annualized Monetized (\$million/year)	(1,328.96)	2021	7	2024–2034
	(1,433.53)	2021	3	2024–2034

F. 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, we estimated that almost all Pharmaceutical and Medicine manufacturers are small entities, as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small

entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having employees of less than 1,250 in any 1 year) for businesses classified in the Pharmaceutical and Medicine Manufacturing industries. Note that the SBA does not provide any revenue data at this time to measure the size of these industries.

According to the SBA's website at <https://www.sba.gov/document/support-table-size-standards>, the drug manufacturers referred to in the

proposed rule fall into both NAICS 325412, Pharmaceutical Preparation Manufacturing and NAICS 325414, Biologic Product (except Diagnostic) Manufacturing. The SBA defines small businesses engaged in pharmaceutical and medicine manufacturing as businesses that have less than 1,250 employees annually for pharmaceutical preparation manufacturing and biologic product (except diagnostic) manufacturing industries. Table 7 presents the total number of small businesses in each of the two industries mentioned.

TABLE 7—NAICS 32541 PHARMACEUTICAL AND MEDICINE MANUFACTURING SIZE STANDARDS

NAICS (6-digit)	Industry subsector description	SBA size standard/ small entity threshold (employees)	Total small businesses
325412	Pharmaceutical Preparation Manufacturing	1,250	2,722
325414	Biologic Product (except Diagnostic)	1,250	587

Source: 2019 Economic Census.

TABLE 8—CONCENTRATION RATIOS (NAICS 325412) PHARMACEUTICAL PREPARATION

Firm size (by number of employees)	Firm count	Percentage of small firms (%)	Total employees	Employee per firm to total employee (%)
Small Firms	2,722	100	93,181	100
02: <5 employees	390	14	633	0.679
03: 5–9 employees	159	6	1,058	1.135
04: 10–14 employees	65	2	752	0.807
05: 15–19 employees	48	2	766	0.822
06: <20 employees	662	24	3,209	3.444
07: 20–24 employees	25	1	535	0.574
08: 25–29 employees	25	1	648	0.695
09: 30–34 employees	19	1	587	0.630
10: 35–39 employees	21	1	700	0.751
11: 40–49 employees	30	1	1,329	1.426
12: 50–74 employees	45	2	2,600	2.790
13: 75–99 employees	31	1	2,439	2.617
14: 100–149 employees	49	2	5,292	5.679
15: 150–199 employees	27	1	3,793	4.071
16: 200–299 employees	42	2	6,853	7.355
17: 300–399 employees	22	1	6,204	6.658
18: 400–499 employees	13	0	3,907	4.193
19: <500 employees	1,011	37	38,096	40.884
20: 500–749 employees	19	1	6,514	6.991
21: 750–999 employees	10	0	3,635	3.901
22: 1,000–1,499 employees	9	0	3,631	3.897
Large firms: Employees >1,499	68	NA	94,707	NA

Source: 2019 Economic Census.

TABLE 9—CONCENTRATION RATIOS (NAICS 325414) BIOLOGIC PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING

Firm size (by number of employees)	Firm count	Percentage of small firms (%)	Total employees	Employee per firm to total employee (%)
Small Firms	587	100	21,789	100
02: <5 employees	71	12	141	0.65
03: 5–9 employees	42	7	282	1.29
04: 10–14 employees	13	2	145	0.67
05: 15–19 employees	13	2	224	1.03
06: <20 employees	139	24	792	3.63
07: 20–24 employees	12	2	261	1.20
08: 25–29 employees	7	1	167	0.77
09: 30–34 employees	6	1	184	0.84
11: 40–49 employees	6	1	247	1.13
12: 50–74 employees	13	2	624	2.86
13: 75–99 employees	5	1	384	1.76
14: 100–149 employees	8	1	799	3.67
15: 150–199 employees	6	1	720	3.30
16: 200–299 employees	8	1	1,561	7.16
18: 400–499 employees	5	1	1,758	8.07
19: <500 employees	219	37	8,012	36.77
20: 500–749 employees	4	1	1,293	5.93
21: 750–999 employees	5	1	1,868	8.57
22: 1,000–1,499 employees	5	1	2,327	10.68
Large firms: Employees >1,499	41	NA	42,822	NA

Source: 2019 Economic Census.

Note. data are not available for businesses with 1,500 to 2,500 employees.

As can be seen in Tables 8 and 9, the economic impacts are disproportionate for small firms. Tables 8 and 9 show the employees for each of the size categories and the employee impact per small entity. For example, in Table 8, 390 of the smallest firms employ only 0.68 percent of the employees in its industry; while, in Table 9, 71 of the smallest firms employ only 0.65 percent of the employees in its industry.

Therefore, as can be seen in Tables 8 and 9, almost all Pharmaceutical and Medicine Manufacturers are small entities as that term is used in the RFA. Additionally, Tables 8 and 9 show the disproportionate impacts among firms, and between small and large firms. In Tables 8 and 9, each industry, Pharmaceutical Preparation Manufacturing and Biologic Product (except Diagnostic) manufacturing (by employment), firm count, percentage of small firms, total employee and percentage of total employee per firm size to total employees of the small firms were estimated separately to determine the Pharmaceutical and Medicine manufacturer concentration ratios.

For purposes of the RFA, approximately 98 percent of Pharmaceutical Preparation Manufacturing (2,722/2,790 firms) and approximately 93 percent of Biologic Product (except Diagnostic) (587/628) firms are considered small businesses according to the SBA's size standards

with 1,250 total employees in any 1 year.

At this time, revenue data are not currently available. However, 2012 revenue data from the U.S. Economic Census were used to obtain a proxy for revenue earned in the Pharmaceutical Preparation Manufacturing industry. Therefore, as of 2012, the total annual receipts for small establishments in the Pharmaceutical Preparation Manufacturing industry, earning less than \$45 million accounted for approximately 3.1 percent of the revenue. Similarly, according to the 2012 data, total annual receipts for small establishments in the Biologic Product (except Diagnostic) accounted for approximately 3.5 percent of the revenue in its industry.

Individuals and States are not included in the definition of a small entity. This final rule will not have a significant impact (that is, a measured change in revenue of 3 to 5 percent) on a substantial number of small businesses or other small entities. 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. At this time, we do not believe that this threshold will be reached by the requirements in the proposed rule. Therefore, the Secretary has certified that the proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not have a significant impact on small rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we have determined, and the Secretary has certified, that the final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately \$183 million.

This final rule imposes mandates that will result in anticipated costs to State, local, and Tribal governments or the private sector, but the transfer costs will be less than the threshold. States will receive additional monetary rebates

from manufacturers brought into compliance with drug misclassification. This final rule will limit the timeframe manufacturers have to dispute rebates, identify patients to the pharmacist as Medicaid beneficiaries, provide transparency to the State as to which PBM costs are true services costs (costs of prescriptions and dispensing fees) versus administrative costs, and permit States to pay claims sooner than the specified waiting period, when doing so is cost-effective and necessary to ensure access to care.

As a result, this final rule will not impose a mandate that would result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$183 million in any 1 year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication, therefore the requirements of Executive Order 13132 are not applicable.

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.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 9, 2024.

List of Subjects

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Citizenship and naturalization, Civil rights, Grant programs—health, Individuals with disabilities, Medicaid, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and

recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 433—STATE FISCAL ADMINISTRATION

■ 1. The authority citation for part 433 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Amend § 433.139 by revising paragraphs (b)(3)(i) and (b)(3)(ii)(B) to read as follows:

§ 433.139 Payment of claims.

* * * * *

(b) * * *

(3) * * *

(i) The claim is for preventive pediatric services, including early and periodic screening, diagnosis and treatment services provided for under part 441, subpart B, of this chapter, that are covered under the State plan that requires a State to make payments without regard to third party liability for pediatric preventive services except that the State may, if the State determines doing so is cost-effective and will not adversely affect access to care, only make such payment if a third party so liable has not made payment within 90 days after the date the provider of such services has initially submitted a claim to such third party for payment for such services; or

(ii) * * *

(B) For child support enforcement services beginning February 9, 2018, the provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited up to 100 days after the date of the service and provider of such services has initially submitted a claim to such third party for payment for such services, except that the State may make such payment within 30 days after such date if the State determines doing so is cost-effective and necessary to ensure access to care.

* * * * *

PART 438—MANAGED CARE

■ 3. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Amend § 438.3 by adding paragraphs (s)(7) and (8) and (w) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(s) * * *

(7) The MCO, PIHP, or PAHP must assign and exclusively use unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits.

(8) The MCO, PIHP, or PAHP that contracts with any subcontractor for the delivery or administration of the covered outpatient drug benefit must require the subcontractor to report separately to the MCO, PIHP, or PAHP the amounts related to:

(i) The incurred claims described in § 438.8(e)(2) such as reimbursement for the covered outpatient drug, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a covered outpatient drug; and

(ii) Administrative costs, fees and expenses of the subcontractor.

* * * * *

(w) *Applicability date.* Paragraphs (s)(7) and (8) of this section apply to the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following November 19, 2024.

* * * * *

PART 447—PAYMENTS FOR SERVICES

■ 5. The authority citation for part 447 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1396r–8.

■ 6. Amend § 447.502 by—

■ a. In the definition of “Covered outpatient drug”:

■ i. In the introductory text, adding “(COD)” immediately following “Covered outpatient drug”; and

■ ii. Revising paragraph (2) introductory text;

■ iii. Adding paragraph (4);

■ b. Adding the definitions of “Drug product information”, “Internal investigation” and “Market date” in alphabetical order; and;

■ c. In the definition of “Noninnovator multiple source drug,” revising paragraph (3).

The revisions and additions read as follows:

§ 447.502 Definitions.

* * * * *

Covered outpatient drug (COD) * * *

(2) A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the services in paragraphs (2)(i) through (viii) of this definition (and for which payment may be made as part of

payment for that service and not as direct reimbursement for the drug, as described in paragraph (4) of this definition).

* * * * *

(4) Direct reimbursement for a drug may include both:

(i) Reimbursement for a drug alone, or
(ii) Reimbursement for a drug plus the service, in a single inclusive payment if:

(A) The drug, charge for the drug, and number of units of the drug are separately identified on the claim, and;

(B) The inclusive payment includes an amount directly attributable to the drug, and,

(C) The amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the State plan.

* * * * *

Drug product information means National Drug Code (NDC), drug name, units per package size (UPPS), drug category (“S”, “I”, “N”), unit type (for example, TAB, CAP, ML, EA), drug type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension indicator, 5i indicator, 5i route of administration (if applicable), FDA approval date, FDA application number or OTC monograph citation (if applicable), market date, and COD status.

* * * * *

Internal investigation means a manufacturer’s investigation of its AMP, best price, customary prompt pay discounts, or nominal prices that have been previously certified in the Medicaid Drug Rebate Program (MDRP) that results in a finding made by the manufacturer of possible fraud, abuse, or violation of law or regulation. A manufacturer must make data available to CMS to support its finding.

* * * * *

Market date, for the purpose of establishing the base date AMP quarter, means the date on which the covered outpatient drug was first sold by any manufacturer.

* * * * *

Noninnovator multiple source drug

* * *

(3) A covered outpatient drug that entered the market before 1962 that is not marketed under an NDA;

* * * * *

■ 7. Amend § 447.504 by revising paragraphs (c)(25) through (29) and (e)(13) through (17) to read as follows:

§ 447.504 Determination of average manufacturer price.

* * * * *

(c) * * *

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that: The voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(28) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(29) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

* * * * *

(e) * * *

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the

extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(17) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

* * * * *

■ 8. Amend § 447.505 by revising paragraphs (c)(8) through (12) to read as follows:

§ 447.505 Determination of best price.

* * * * *

(c) * * *

(8) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession.

(10) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.

(12) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

* * * * *

■ 9. Amend § 447.509 by—

■ a. Revising paragraphs (a)(5), (a)(6) introductory text, (a)(7) introductory text, (a)(8) and (9), and (c)(4); and

■ b. Adding paragraph (d).

The revisions and addition read as follows:

§ 447.509 Medicaid drug rebates (MDR).

(a) * * *

(5) *Limit on rebate.* For a rebate period beginning after December 31, 2009, and before January 1, 2024, in no case will the total rebate amount exceed 100 percent of the AMP of the single source or innovator multiple source drug.

(6) *Rebate for drugs other than a single source drug or innovator multiple source drug.* The amount of the basic rebate for each dosage form and strength of a drug other than a single source drug or innovator multiple source drug will be equal to the product of:

* * * * *

(7) *Additional rebate for drugs other than a single source drug or innovator multiple source drug.* In addition to the basic rebate described in paragraph (a)(6) of this section, for each dosage form and strength of a drug other than a single source drug or innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

* * * * *

(8) *Total rebate.* The total rebate amount for a drug other than a single source drug or innovator multiple source drug is equal to the basic rebate amount plus the additional rebate amount, if any.

(9) *Limit on rebate.* For a rebate period beginning after December 31, 2014, and before January 1, 2024, in no case will the total rebate amount exceed 100 percent of the AMP for a drug other than a single source drug or innovator multiple source drug.

* * * * *

(c) * * *

(4) For a drug other than a single source drug or innovator multiple source drug, the offset amount is equal to 2.0 percent of the AMP (the difference between 13.0 percent of AMP and 11.0 percent of AMP).

(d) *Manufacturer misclassification of a covered outpatient drug and recovery of unpaid rebate amounts due to the misclassification and other penalties—*

(1) *Definition of misclassification.* A misclassification in the MDRP has occurred when a manufacturer has:

(i) Reported and certified to the agency its drug category or drug product information related to a covered outpatient drug that is not supported by the statute and applicable regulations; or,

(ii) Reported and certified to the agency its drug category or drug product information that is supported by the statute and applicable regulations, but pays rebates to States at a level other than that associated with that classification.

(2) *Manufacturer notification by the agency of drug misclassification.* If the agency determines that a misclassification has occurred as described in paragraph (d)(1) of this section, the agency will send written and electronic notification of this misclassification to the manufacturer of the covered outpatient drug, which may include a notification that past rebates are due. The manufacturer has 30 calendar days from the date of notification to:

(i) Provide the agency such drug product and drug pricing information needed to correct the misclassification of the covered outpatient drug and calculate rebate obligations due, if any, pursuant to paragraph (d)(3) of this section. The required pricing data submitted by the manufacturer to the agency shall include the best price information for the covered outpatient drug, if applicable, for the rebate periods for which the manufacturer misclassified the covered outpatient drug; and,

(ii) Certify applicable price and drug product data after entered into the system by the agency.

(3) *Manufacturer payment of unpaid rebates due to misclassification determined by agency.*

(i) When the agency has determined that a manufacturer has misclassified a covered outpatient drug as described in paragraph (d)(1) of this section, such that rebates are owed to the States, and notification has been provided to the manufacturer as provided under paragraph (d)(2) of this section, a manufacturer must pay to each State an amount equal to the sum of the products of:

(A) The difference between:

(1) The per URA paid by the manufacturer for the covered outpatient drug to the State for a period during which the drug was misclassified; and

(2) The per URA that the manufacturer would have paid to the State for the covered outpatient drug for each period, as determined by the agency based on the data provided and certified by the manufacturer under paragraph (d)(2) of this section, if the drug had been correctly classified by the manufacturer; and,

(B) The total units of the drug paid for under the State plan in each period.

(ii) Manufacturers must pay such rebates to the States for the period or

periods of time that such covered outpatient drug was misclassified, based on the formula described in this section, within 60 calendar days of notification by the agency to the manufacturer of the misclassification, and provide documentation to the agency that the States were contacted by the manufacturer, and that such payments were made to the States within the 60 calendar days.

(4) *Agency authority to correct misclassifications and additional penalties for drug misclassification.* The agency will review the information submitted by the manufacturer based on the notice sent under paragraph (d)(2) of this section. If a manufacturer fails to comply with paragraph (d)(2) of this section within 30 calendar days from the date of the notification by the agency of the misclassification to the manufacturer under paragraph (d)(1) of this section, fails to pay the rebates that are due to the States as a result of the misclassification within 60 calendar days from the date of the notification, if applicable, and/or fails to provide to the agency such documentation that such rebates have been paid, as described in paragraph (d)(3) of this section, the agency may do any or all of the following:

(i) Correct the misclassification of the drug in the system on behalf of the manufacturer, using any pricing and drug product information that may have been provided by the manufacturer. In such case, the manufacturer must certify the applicable correction within 30 calendar days.

(ii) Suspend the misclassified drug and the drug's status as a covered outpatient drug under the manufacturer's rebate agreement from the MDRP, and exclude the misclassified drug from FFP in accordance with section 1903(i)(10)(E) of the Act.

(iii) Impose a civil monetary penalty (CMP) for each rebate period during which the drug is misclassified, not to exceed an amount equal to the product of:

(A) The total number of units of each dosage form and strength of such misclassified drug paid for under any State plan during such a rebate period; and

(B) 23.1 percent of the AMP for the dosage form and strength of such misclassified drug for that period.

(iv) Other actions and penalties available under section 1927 of the Act (or any other provision of law), including referral to the HHS Office of the Inspector General and termination from the MDRP.

(5) *Transparency of manufacturers' drug misclassifications.* The agency will make available on a public website an annual report as required under section 1927(c)(4)(C)(ii) of the Act on the covered outpatient drug(s) that were identified as misclassified during the previous year, any steps taken by the agency with respect to the manufacturer to reclassify the drugs and ensure the payment by the manufacturer of unpaid rebate amounts resulting from the misclassifications, and a disclosure of the expenditures from the fund created in section 1927(b)(3)(C)(iv) of the Act.

■ 10. Amend § 447.510 by –

■ a. Revising the section heading and paragraph (b)(1)(v);

■ b. Adding paragraphs (h) and (i).

The revisions and additions read as follows:

§ 447.510 Requirement and penalties for manufacturers.

* * * * *

(b) * * *

(1) * * *

(v) The change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation as defined at § 447.502, or an Office of Inspector General (OIG) or Department of Justice investigation.

* * * * *

(h) *Suspension of manufacturer's NDRA for late reporting of drug pricing and drug product information.*

(1) If a manufacturer fails to timely provide information required to be reported to the agency under section 1927(b)(3)(A) of the Act, and paragraphs (a) and (d) of this section, the agency will provide written notice to the manufacturer of failure to provide timely information. If such information is not reported within 90 calendar days of the date of the notice communicated to the manufacturer electronically and in writing by the agency, such failure by the manufacturer to report such information in a timely manner shall result in suspension of the manufacturer's rebate agreement for all covered outpatient drugs furnished after the end of the 90-day calendar period. The rebate agreement will remain suspended until the date the information is reported to the agency in full and certified, and the agency reviews for completeness, but not for a period of fewer than 30 calendar days. Continued suspension of the rebate agreement could result in termination for cause. Suspension of a manufacturer's rebate agreement under this section applies for Medicaid purposes only and does not affect manufacturer obligations and

responsibilities under the 340B Program or reimbursement under Medicare Part B during the period of the suspension.

(2) During the period of the suspension, the covered outpatient drugs of the manufacturer are not eligible for FFP. The agency will notify the States 30 calendar days before the beginning of the suspension period for the manufacturer's rebate agreement and any applicable associated labeler rebate agreements.

(i) *Manufacturer audits of State-provided information.* A manufacturer may only initiate a dispute, request a hearing, or seek an audit of a State regarding State drug utilization data, during a period not to exceed 12 quarters from the last day of the quarter from the State invoice postmark date.

■ 11. Amend § 447.518 by adding a heading to paragraph (d) and revising paragraph (d)(1) to read as follows:

§ 447.518 State plan requirements, findings, and assurances.

* * * * *

(d) *Data requirements.* (1) When proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, States are required to evaluate their proposed changes in accordance with the requirements of this subpart, and States must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act. States must provide adequate cost-based data, such as a State or national survey of retail pharmacy providers or other reliable cost-based data other than a survey, to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment formal review process. Research and data must be based on pharmacy costs and be sufficient to establish the adequacy of both current ingredient cost reimbursement and professional dispensing fee reimbursement. Submission by the State of data that are not based on pharmacy costs, such as market-based research (for example, third party payments accepted by pharmacies), to support the professional dispensing fee would not qualify as supporting data.

* * * * *

■ 12. Section 447.520 is revised to read as follows:

§ 447.520 Federal Financial Participation (FFP): Conditions relating to physician-administered drugs.

(a) *Availability of FFP.* No FFP is available for physician-administered single source drugs or the multiple source drugs identified under paragraph (c) of this section that are covered outpatient drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to invoice a manufacturer for rebates in a manner consistent with the requirements of this section. In the case of multiple source drugs not identified under paragraph (c), a failure to comply with the requirements of this section may result in FFP being withheld as provided under 42 CFR 430.35.⁴⁰

(1) *Single source drugs.* For a covered outpatient drug that is a single source, physician-administered drug, administered on or after January 1, 2006, a State must require providers to submit claims for using National Drug Code (NDC) numbers to secure rebates and receive FFP.

(2) *Multiple source drugs.* For a covered outpatient drug that is a multiple source, physician-administered drug on the list published by CMS described in paragraph © of this section, administered on or after January 1, 2008, a State must require providers to submit claims using NDC numbers to secure rebates and receive FFP.

(3) States are required to invoice for rebates consistent with this section for multiple source physician-administered drugs that are CODs and that are not on the top 20 multiple source physician-administered drug list published under paragraph (c) of this section, or may be subject to a withhold of FFP as provided under 42 CFR 430.35.⁴¹

(b) *Required coding.* As of January 1, 2007, a State must require providers to submit claims for a covered outpatient drug that is described in paragraph (a)(1) or (2) of this section that is a physician-administered drug using NDC numbers. As of November 19, 2024, a State must also comply with this requirement for a covered outpatient drug that is a physician-administered drug described in paragraph (a)(3) of this section.

(c) *Top 20 multiple source physician-administered drug list.* The top 20 multiple source physician-administered drug list, identified by the Secretary as

⁴⁰ <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-430>.

⁴¹ Ibid.

having the highest dollar volume of physician-administered drugs dispensed under the Medicaid program, will be published and may be modified from

year to year to reflect changes in such volume.

(d) *Hardship waiver.* A State that requires additional time to comply with

the requirements of this section may apply to the Secretary for an extension.

Xavier Becerra,
Secretary, Department of Health and Human Services.

[FR Doc. 2024–21254 Filed 9–20–24; 4:15 pm]

BILLING CODE 4120–01–P



FEDERAL REGISTER

Vol. 89

Thursday,

No. 187

September 26, 2024

Part IV

Department of Commerce

Bureau of Industry and Security

15 CFR Part 791

Securing the Information and Communications Technology and Services
Supply Chain: Connected Vehicles; Proposed Rule

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 791

[Docket No. 240919–0245]

RIN 0694–AJ56

Securing the Information and Communications Technology and Services Supply Chain: Connected Vehicles**AGENCY:** Bureau of Industry and Security, Department of Commerce.**ACTION:** Notice of proposed rulemaking.

SUMMARY: In this notice of proposed rulemaking (NPRM), the Department of Commerce's (Department) Bureau of Industry and Security (BIS) proposes a rule to address undue or unacceptable risks to national security and U.S. persons posed by classes of transactions involving information and communications technology and services (ICTS) that are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of certain foreign adversaries, and which are integral to connected vehicles, as defined herein. BIS is soliciting comment on this proposed rule, which builds on the advance notice of proposed rulemaking (ANPRM) issued by BIS on March 1, 2024.

DATES: Comments to this proposed rule must be received on or before October 28, 2024.

ADDRESSES: All comments must be submitted by one of the following methods:

- *By the Federal eRulemaking Portal:* <http://www.regulations.gov> at docket number BIS–2024–0005.

- *By email directly to:* connectedvehicles@bis.doc.gov. Include “RIN 0694–AJ56” in the subject line.

- *Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. For those seeking to submit confidential business information (CBI), please clearly mark such submissions as CBI and submit by email, as instructed above. Each CBI submission must also contain a summary of the CBI, clearly marked as public, in sufficient detail to permit a reasonable understanding of the substance of the information for public consumption. Such summary information will be posted on [regulations.gov](http://www.regulations.gov). Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

- The Regulatory Impact Analysis is available at <http://www.regulations.gov> at docket number BIS–2024–0005.

FOR FURTHER INFORMATION CONTACT:

Marc Coldiron, U.S. Department of Commerce, telephone: (202) 482–3678. For media inquiries: Jessica Stallone, Office of Congressional and Public Affairs, Bureau of Industry and Security, U.S. Department of Commerce: OCA@bis.doc.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In this notice, BIS solicits comment on a proposed rule to prohibit transactions involving Vehicle Connectivity System (VCS) hardware and covered software designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the People's Republic of China, including the Hong Kong Special Administrative Region (PRC), or the Russian Federation (Russia). It follows an advance notice of proposed rulemaking (ANPRM), 89 FR 15066 (Mar. 1, 2024), in which BIS sought public comment to inform a rulemaking that would address the undue or unacceptable risks, as identified in Executive Order (E.O.) 13873, “Securing the Information and Communications Technology and Services Supply Chain,” 84 FR 22689 (May 17, 2019), posed by a class of transactions that involve information and communications technology and services (ICTS) designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary and integral to Connected Vehicles.

In E.O. 13873, the President delegated to the Secretary of Commerce (Secretary), to the extent necessary to implement the order, the authority granted under the International Emergency Economic Powers Act (IEEPA) (50 U.S.C. 1701, *et seq.*), “to deal with any unusual and extraordinary” foreign threat to the United States’ national security, foreign policy, or economy, if the President declares a national emergency with respect to such threat. 50 U.S.C. 1701(a). In E.O. 13873, the President declared a national emergency with respect to the “unusual and extraordinary” foreign threat posed to the ICTS supply chain and has, in accordance with the National Emergencies Act (NEA), extended the declaration of this national emergency in each year since E.O. 13873’s publication. *See Continuation of the National Emergency With Respect*

to Securing the Information and Communications Technology and Services Supply Chain, 85 FR 29321 (May 14, 2020); *Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain*, 86 FR 26339 (May 13, 2021); *Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain*, 87 FR 29645 (May 13, 2022); *Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain*, 88 FR 30635 (May 11, 2023); *Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain*, 89 FR 40353 (May 9, 2024).

Specifically, the President identified the “unrestricted acquisition or use in the United States of ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of foreign adversaries” as “an unusual and extraordinary” foreign threat to the national security, foreign policy, and economy of the United States that “exists both in the case of individual acquisitions or uses of such technology or services, and when acquisitions or uses of such technologies are considered as a class.” *See* E.O. 13873, and 50 U.S.C. 1701(a)–(b).

Once the President declares a national emergency, IEEPA empowers the President to, among other acts, investigate, regulate, prevent, or prohibit, any “acquisition, holding, withholding, use, transfer, withdrawal, transportation, importation or exportation of, or dealing in, or exercising any right, power, or privilege with respect to, or transactions involving, any property in which any foreign country or a national thereof has any interest by any person, or with respect to any property, subject to the jurisdiction of the United States.” 50 U.S.C. 1702(a)(1)(B).

To address the identified risks to national security from ICTS transactions, the President in E.O. 13873 imposed a prohibition on transactions determined by the Secretary, in consultation with relevant agency heads, to involve foreign adversary ICTS and to pose certain risks to U.S. national security, technology, or critical infrastructure. Specifically, to fall within the scope of the prohibition, the Secretary must determine that a transaction: (1) “involves [ICTS]

designed, developed, manufactured, or supplied, by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary,” defined in E.O. 13873 as “any foreign government or foreign non-government person engaged in a long-term pattern or serious instances of conduct significantly adverse to the national security of the United States or security and safety of United States persons;” and (2):

A. “Poses an undue risk of sabotage to or subversion of the design, integrity, manufacturing, production, distribution, installation, operation, or maintenance of information and communications technology or services in the United States;”

B. “Poses an undue risk of catastrophic effects on the security or resiliency of United States critical infrastructure or the digital economy of the United States;” or

C. “Otherwise poses an unacceptable risk to the national security of the United States or the security and safety of United States persons.”

These factors are collectively referred to as “undue or unacceptable risks.” Further, E.O. 13873 grants the Secretary the authority to design or negotiate mitigation measures that would allow an otherwise prohibited transaction to proceed. E.O. 13873 section 1(b).

The President also delegated to the Secretary the ability to promulgate regulations that, among other things, establish when transactions involving particular technologies may be categorically prohibited. E.O. 13873 section 2(a)–(b); *see also* 3 U.S.C. 301–02. Specifically, the Secretary may issue rules establishing criteria, consistent with section 1 of E.O. 13873, by which particular technologies or market participants may be categorically included in or categorically excluded from prohibitions established pursuant to E.O. 13873.

II. Introduction

Today’s vehicles contain a myriad of connected components that provide greater convenience for consumers and increase road safety for both drivers and pedestrians, such as Wi-Fi, Bluetooth, cellular, and satellite connectivity. However, the incorporation of progressively more complex hardware and software systems that facilitate these features has also increased the attack surfaces through which malign actors may exploit vulnerabilities to gain access to a vehicle. As BIS outlined in its March 1, 2024, ANPRM, certain ICTS integral to Connected Vehicles could present an undue or unacceptable risk to U.S. national security when those

systems are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary.

In the *Securing the Information and Communications Technology and Services Supply Chain* interim final rule, 86 FR 4909 (January 19, 2021), the Secretary determined that certain foreign governments or foreign non-government persons including the PRC, Republic of Cuba, Islamic Republic of Iran, Democratic People’s Republic of Korea, Russia, and Venezuelan politician Nicolás Maduro constitute foreign adversaries for purposes of E.O. 13873 and rules promulgated pursuant to E.O. 13873. *See* 15 CFR 791.4 (to the extent that the list of foreign adversaries identified in 15 CFR 791.4 is updated to add or remove governments or non-government persons, this proposed rule intends to reflect the most up-to-date designations of foreign adversaries). Additionally, E.O. 13873 provides that the Secretary may issue rules that identify particular technologies or countries with respect to which transactions involving ICTS warrant particular scrutiny. E.O. 13873 2(b). For the purposes of this proposed rule regarding transactions involving ICTS integral to Connected Vehicles, BIS is focusing its regulatory efforts on ICTS that are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. BIS has identified that, for the purposes of addressing the national security risks posed by Connected Vehicles, these two foreign adversaries pose particular risks to U.S. national security because of their legal, political, and regulatory regimes, combined with their current and anticipated growth and involvement in the automotive sector, to include Connected Vehicles. However, BIS specifically seeks public comment on whether the other identified foreign adversaries pose similar risks to U.S. national security in the connected vehicle supply chain.

The PRC and Russia are able to leverage domestic legislation and regulatory regimes to compel companies subject to their jurisdiction, including carmakers and their suppliers, to cooperate with security and intelligence services. Such control over companies and their products and services means that equipment is easily exploitable by PRC and Russian authorities. The privileged access that the PRC and Russia may gain to Connected Vehicles through their components, including software, could enable those foreign adversaries to exfiltrate sensitive data

collected by connected vehicles and, potentially, allow remote access and manipulation of connected vehicles driven by U.S. persons. Pursuant to E.O. 13873, BIS has determined that certain classes of transactions that facilitate the exfiltration of data and remote manipulation of connected vehicles pose undue or unacceptable risks to U.S. national security and the safety and security of U.S. persons.

a. Overview of Proposed Rule

To address these identified undue or unacceptable risks, BIS is proposing regulations that would, absent a General or Specific Authorization, (1) prohibit VCS Hardware Importers from knowingly importing into the United States certain hardware for VCS (“VCS Hardware,” as further defined below); (2) prohibit connected vehicle manufacturers from knowingly importing into the United States completed connected vehicles incorporating certain software that supports the function of VCS or ADS (VCS and ADS software are collectively referred to herein as “covered software,” as further defined below); (3) prohibit connected vehicle Manufacturers from knowingly Selling within the United States completed connected vehicles that incorporate covered software; and (4) prohibit connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia from knowingly selling in the United States completed connected vehicles that incorporate VCS hardware or covered software. The prohibitions would apply when such VCS hardware or covered software is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

If, following consideration of comments received on this proposed rule, BIS issues a final rule to adopt the proposal, that final rule would take effect 60 days after publication in the **Federal Register**. However, VCS Hardware Importers would be permitted to engage in otherwise Prohibited Transactions involving VCS Hardware and exempt from certain requirements so long as: (1) for VCS Hardware not associated with a Model Year, the import of the VCS Hardware takes place prior to January 1, 2029; or (2) the VCS Hardware unit is associated with a vehicle Model Year prior to 2030 or the VCS Hardware is integrated into a connected vehicle (completed or incomplete) with a Model Year prior to 2030. connected vehicle manufacturers would be permitted to engage in

otherwise prohibited transactions involving covered software and exempt from certain requirements, so long as the completed connected vehicle that is imported, or sold within the United States, is of a model year prior to 2027. connected vehicle Manufacturers that are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia would be permitted to sell completed connected vehicles with a model year prior to 2027 that incorporate VCS hardware or covered software.

BIS is also proposing to implement several mechanisms to facilitate compliance with these prohibitions: (1) Declarations of Conformity submitted to BIS by VCS hardware importers and connected vehicle manufacturers to confirm that they are not engaging in prohibited transactions involving VCS hardware or covered software, as defined herein; (2) Advisory opinions to allow VCS hardware importers and connected vehicle manufacturers to seek guidance from BIS on whether a prospective transaction may be prohibited; (3) General authorizations to allow certain VCS hardware importers and connected vehicle manufacturers to engage in otherwise prohibited transactions without the need to notify BIS prior to the prohibited activity if they qualify under stated conditions; (4) Specific authorizations which, following an application to and approval by BIS, grant VCS hardware importers and connected vehicle manufacturers the ability to engage in otherwise prohibited transactions, including because the associated undue or unacceptable risks have been, or can be, mitigated; and (5) A process to inform VCS hardware importers and connected vehicle manufacturers that a specific authorization may be required because an activity could constitute a Prohibited Transaction.

This proposed rule benefits from the responses received during the public comment period for the ANPRM and incorporates significant portions of that feedback. For example, BIS considered public feedback to define the scope of connected vehicles, identify ICTS integral to Connected Vehicles, and better understand the effects of any potential prohibition. Determining the scope of the prohibitions outlined in this proposed rule required balancing the need to address the undue or unacceptable risk posed by foreign adversary involvement in the connected vehicles supply chain with the impact on the public and industry.

III. Comments on the Advance Notice of Proposed Rulemaking

On March 1, 2024, the Department published in the **Federal Register** an ANPRM, 89 FR 15066, pursuant to the authority the President delegated to the Secretary in E.O. 13873. The purpose of the ANPRM was to solicit stakeholder feedback and to gather information to further BIS's consideration of a proposed rule to address any undue or unacceptable risks to U.S. national security posed by ICTS used in connected vehicles, when designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary. Specifically, BIS sought public input on certain definitions, capabilities of connected vehicles that may increase the likelihood of vulnerabilities, and consequences to U.S. persons and critical infrastructure if these vulnerabilities are exploited by a foreign adversary. BIS also solicited input on the ICTS most integral to connected vehicles and most vulnerable to compromise, as well as input on mechanisms to address identified risks through potential design, implementation standards and protocols, manufacturing integrity protection systems and procedures, or prohibitions.

BIS received 57 comment submissions in response to the ANPRM, from original equipment manufacturers (OEMs), component suppliers, two foreign governments, nonprofit organizations, and individuals. Five comments contained CBI, and one comment was retracted at the request of the commenter. Each of the comments is available on the public rulemaking docket at <https://www.regulations.gov>.

In general, commenters expressed agreement with BIS on the overall risks posed by compromised ICTS in Connected Vehicles, as outlined in the ANPRM. Commenters were also generally aligned on the need for further clarity on what would constitute a person "owned by, controlled by, or subject to the jurisdiction or direction" of a foreign adversary, the challenge of implementing due diligence requirements due to the complexity of the global automotive supply chain, the need for substantial lead time to implement a regulation given the difficulty of sourcing alternative suppliers, the breadth and depth of data collected by ICTS integral to Connected Vehicles, and the potential negative impact such a regulation could have on long-term U.S. innovation, competitiveness, and health and safety.

On the other hand, commenters disagreed on a number of issues, including the ICTS most integral to connected vehicles, the level of risk that may be posed by transactions involving the identified connected vehicle systems, the definition of connected vehicle, and approaches for how the proposed rule could be most effective in risk mitigation.

Below, BIS addresses in more detail the key issues raised by the comments received and describes how they were considered and, where applicable, addressed in the proposed rule.

a. Definitions

In the ANPRM, BIS sought comments on the definition of the term "connected vehicle," proposing to define it as "an automotive vehicle that integrates onboard networked hardware with automotive software systems to communicate via dedicated short-range communication, cellular telecommunications connectivity, satellite communication, or other wireless spectrum connectivity with any other network or device." Commenters offered differing views on BIS's proposed definition with some, but not all, commenters agreeing that it appropriately captured the platform BIS seeks to regulate.

Commenters that disagreed with BIS's proposed definition offered several reasons. For example, many commenters viewed the term as overly broad and noted that it failed to identify the specific types of vehicles that would be captured by a regulation (*e.g.*, commercial, industrial, agricultural, rolling stock). Commenters also noted that the phrase "connected vehicle" is an existing term of art within the automotive industry referring to vehicles with external communication capabilities, particularly in short-range communication. As an alternative, some commenters suggested that BIS adopt the term "networked vehicle" to capture the ability of a vehicle to communicate with networks or devices external to a vehicle while others suggested the term "software-defined vehicles" which would encompass the technologies and capabilities outlined in the ANPRM's proposed connected vehicle definition while also capturing internal software capabilities for functions within a vehicle beyond communication (*e.g.*, starting a vehicle, malfunction checks, navigation).

After full consideration of each of the comments, BIS maintains the use of the term "connected vehicle" in the proposed rule. However, BIS proposes to narrow its definition to mean, "[a] vehicle driven or drawn by mechanical

power and manufactured primarily for use on public streets, roads, and highways, that integrates onboard networked hardware with automotive software systems to communicate via dedicated short-range communication, cellular telecommunications connectivity, satellite communication, or other wireless spectrum connectivity with any other network or device. Vehicles operated only on a rail line are not included in this definition.” This definition captures the vehicles that would be subject to the rule (*e.g.*, passenger vehicles, motorcycles, buses, small and medium trucks, class 8 commercial trucks, recreational vehicles), while excluding those that pose a less acute risk of data exfiltration, modification, or sabotage by foreign adversaries. BIS further believes that the term connected vehicle, as defined in this proposed rule, will capture future trends in vehicle development, particularly as software comes to play a larger role in vehicle operation. BIS emphasizes its belief that, with very few exceptions, all new vehicles sold in the United States will be captured by this definition. BIS seeks comment on this assessment. In the interest of issuing a rule that is narrow, yet also would address the risks posed by connected vehicles, BIS declines to extend this definition to all “rolling stock” or unmanned aerial vehicles as suggested by some comments, although BIS does not preclude the possibility of addressing these vehicles in future regulation. BIS believes that these sectors, to include vehicles operating on a rail line, are materially different from the connected vehicle sector as defined by this proposed rule, and capturing these vehicles in a regulation primarily targeting wheeled on-road vehicles could lead to unintended consequences and supply chain disruption.

A subset of commenters requested further clarity on what would constitute an entity “subject to the jurisdiction or direction” of a foreign adversary and expressed concerns that foreign subsidiaries of U.S. businesses or foreign nationals working in the United States would potentially be captured by this term. Others suggested that BIS should ensure that the subsidiaries of companies located in foreign adversary countries are captured by the proposed rule, even when the subsidiaries are located in third countries outside the United States that are not foreign adversaries, but supply entities within the United States.

After full consideration of the comments, BIS has adopted the definition of a “person owned by, controlled by, or subject to the

jurisdiction or direction of a foreign adversary” to mean, (a) any person, wherever located, who acts as an agent, representative, or employee, or any person who acts in any other capacity at the order, request, or under the direction or control, of a foreign adversary or of a person whose activities are directly or indirectly supervised, directed, controlled, financed, or subsidized in whole or in majority part by a foreign adversary; (b) any person, wherever located, who is a citizen or resident of a foreign adversary or a country controlled by a foreign adversary, and is not a United States citizen or permanent resident of the United States; (c) any corporation, partnership, association, or other organization with a principal place of business in, headquartered in, incorporated in, or otherwise organized under the laws of a foreign adversary or a country controlled by a foreign adversary; or (d) any corporation, partnership, association, or other organization, wherever organized or doing business, that is owned or controlled by a foreign adversary, to include circumstances in which any person identified in paragraphs (a) through (c) possesses the power, direct or indirect, whether or not exercised, through the ownership of a majority or a dominant minority of the total outstanding voting interest in an entity, board representation, proxy voting, a special share, contractual arrangements, formal or informal arrangements to act in concert, or other means, to determine, direct, or decide important matters affecting an entity. BIS has also provided, below in Section V, numerous non-exhaustive examples to explain how this term will apply in various representative situations.

b. ICTS Supply Chain for Connected Vehicles

In the ANPRM, BIS sought comments on “the ICTS supply chain for Connected Vehicles in the United States,” in order to better understand the role played by persons owned by, controlled by, or subject to the jurisdiction or direction of foreign adversaries within it. Public comments broadly discussed the ICTS incorporated into Connected Vehicles and noted the difficulty that manufacturers and suppliers may face in conducting supply chain due diligence for the purposes of complying with any potential final rule. Submissions explained the complexity of ICTS systems contained within Connected Vehicles and outlined several categories of technologies incorporated into Connected Vehicles,

including microcontrollers, applications processors, analog products (*e.g.*, power management integrated circuits and transceiver physical layers), automotive software operating systems (OS), automotive vision, light detection and ranging (LiDAR) systems, radar, and other application software systems. Many commenters who identified as OEMs also noted that they do not always know the source of all inputs from hardware and software suppliers, making conducting due diligence beyond tier one and tier two suppliers particularly difficult. Moreover, submissions highlighted that suppliers are often capable of updating the firmware on their components independently of an OEM, further complicating efforts to understand which entities have access to software and when such access occurs.

The comments received on this topic highlight the depth and complexity of connected vehicle supply chains, indicating that it is not always clear to OEMs which suppliers have access to connected vehicle software and when they have access to it. As some commenters pointed out, some of these technologies and their associated supply chains are still in development and will grow even more complex as the industry develops. Such existing and growing complexity, coupled with the likelihood of ICTS that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary being incorporated into connected vehicles, demonstrates the need for regulation to protect U.S. national security. Such regulation will also incentivize greater supply chain transparency for not only existing supply chains but also for developing supply chains. To facilitate compliance, the rule would include a delayed implementation timeline so that industry can adjust their existing supply chains and plans for future supply chains. BIS is not currently proposing specific due diligence requirements. Instead, VCS hardware importers and connected vehicle manufacturers are given flexibility to provide evidence of compliance efforts tailored to their unique operations. Such efforts could include using third-party researchers or independently conducting supply chain diligence.

Several commenters raised a variety of potential trade-related concerns relating to this proposed rulemaking and other recent U.S. government actions related to automotive trade involving the PRC. While some commenters explicitly advocated for exclusionary tariffs on the import of all

PRC vehicles into the United States, others cautioned BIS to avoid creating unnecessary trade barriers when crafting a proposed rule. One commenter specifically warned that BIS regulation of connected vehicle software could amount to a digital trade barrier and urged BIS to avoid certain policies such as data localization requirements, digital service taxes, or forced code inspection. BIS underscores the U.S. government's commitment to the trusted and secure flow of data across borders. This proposed rule seeks to narrowly address, pursuant to E.O. 13873, the acute national security concerns posed by certain foreign adversary ICTS in connected vehicle supply chains while minimizing any unnecessary disruptions in manufacturing and trade. BIS has drafted this proposed rule irrespective of any other automobile-related trade actions taken by the U.S. government.

c. ICTS Most Integral to Connected Vehicles and Their Capabilities

In its ANPRM, BIS identified six systems (*i.e.*, vehicle operating systems (OS), telematics systems, Advanced Driver-Assistance System (ADAS), Automated Driving Systems (ADS), satellite or cellular telecommunications systems, and battery management systems (BMS)) that it was considering identifying as the ICTS in Connected Vehicles most likely to present undue or unacceptable risks if exploited by foreign adversaries. BIS requested comment on the levels of risk associated with these various ICTS as well as any additional ICTS that commenters might consider integral to Connected Vehicles.

Commenters held differing views on which ICTS are integral to connected vehicles and should be captured by the scope of a rule. For example, whereas some commenters noted that ADAS present a low risk of data exfiltration given that these systems often lack direct external connectivity, others noted that such systems may nevertheless be indirectly connected to external devices and systems (*e.g.*, microcontrollers), thus offering indirect access to the data they collect. As another example, while many commenters identified LiDAR systems as a concern, there was disagreement about the nature of the vulnerability posed by these systems. Some commenters noted that LiDAR systems could be manipulated to cause grave harm (*e.g.*, to ignore pedestrians) given their instrumental role in vehicle guidance. However, BIS's further technical analysis found that LiDAR generally lacks the ability to transmit from the vehicle and does not, as a

standalone system, control the vehicle. Importantly, BIS notes that in many cases, ADS exerts control over both LiDAR and the vehicle and thus presents a higher risk. Other commenters pointed to the growing role of mobile applications that allow drivers to access and control core functions of the vehicle remotely (*e.g.*, keyless driving). A number of commenters also highlighted concerns related to aftermarket connected devices. These devices, which often feature some forms of connectivity, are introduced to the vehicle after manufacture and sale and may contain vulnerabilities over which OEMs have little to no oversight.

Several submissions expressed a desire for BIS to tailor any regulation as narrowly as possible, arguing that BIS should focus only on those systems with direct connectivity to the connected vehicle or the ability to transmit from the connected vehicle. Some commenters pointed specifically to devices that connect to a vehicle's controller area network (CAN) bus as posing a specific cybersecurity risk. Others recommended that BIS should critically examine electric vehicle charging infrastructure and associated technologies due to a potential risk of exploitation by foreign adversaries. A few OEM commenters ascribed the highest level of potential risk to "finished" or "vertically integrated" vehicles from suppliers with a foreign adversary nexus that are operating in the United States. One commenter pointed to ICTS components inside safety-critical systems (*e.g.*, braking systems, steering systems, traction systems, battery-charging and management systems, airbag systems) as posing greater levels of potential risk. On the other hand, some commenters recommended that BIS should aim to address the widest possible aperture of risk by regulating a wide variety of the technologies enumerated in the ANPRM along with additional technology categories (*e.g.*, microcontrollers, analog products).

Following consideration of these comments, BIS is proposing a rule that aims to strike a balance between minimizing supply chain disruptions and the need to address the national security risks posed by Connected Vehicles. BIS proposes to achieve this balance by focusing the rule only on those systems that most directly facilitate the transmission of data both into and from the vehicle, rather than focusing on all systems. Therefore, BIS is proposing to regulate transactions involving two systems of ICTS integral to connected vehicles, VCS and ADS. As further discussed below, in many cases,

these systems serve as controllers for subordinate systems within the Connected Vehicle, like those highlighted in the ANPRM, making them a target for exploitation related to data exfiltration or remote vehicle manipulation. After reviewing comments, BIS has determined that aftermarket telematics devices, including fleet tracking devices and systems, that fulfill functions consistent with the definition of VCS hardware are covered by this proposed rule.

Additionally, the proposed rule does not cover ICTS with the function of enabling the transmission, receipt, conversion, or processing of radio frequency communications at a frequency below 450 megahertz. Setting such a threshold enables BIS to capture those ICTS that pose a higher risk due to their connectivity and transmission functions, while lowering compliance burden by excluding from regulation those ICTS with functions that pose a lower risk and offer high utility to consumers (*e.g.*, tire pressure monitoring systems, electronic key fobs).

For similar reasons, BIS ultimately chose to exclude other systems highlighted in the ANPRM—such as OS, ADAS, or BMS—from this proposed rule unless they have VCS components and fall within the proposed rule's definition of VCS hardware. For example, automotive software systems like BMS and automotive OS do not have their own connectivity, and require communication through a VCS, thereby making VCS a more effective focus for rulemaking. BMS traditionally do not have their own external wireless data link and instead rely on VCS for wireless communication through a VCS. Likewise, automotive OS software, which generally resides on an in-vehicle infotainment unit or centralized head unit, are characterized by a wide diversity in architecture, design, and supply chain among OEMs while also generally lacking their own data link, instead relying on communication through a VCS. Given how these systems are typically placed within connected vehicles and the ways in which they achieve connectivity, BIS has chosen to focus on the systems that ultimately facilitate the transmission of data both to and from the vehicle as opposed to these subordinate systems.

Additionally, to reduce unnecessary economic impacts and supply disruption, BIS is proposing to regulate ADS software rather than the hardware components of ADAS and ADS. The hardware that enables ADAS and ADS varies widely between different OEMs. In contrast, the hardware that enables

VCS are relatively consistent across different automotive architectures and designs. ADAS and ADS hardware encompasses a wide variety of different sensors, distributed electronic control units (ECUs), centralized computing units, actuators, and signaling units, among others. These sensors and internal vehicle networking hardware rarely have independent connectivity. Most, if not all, scalable cybersecurity vulnerabilities to these systems are achieved by connectivity through VCS systems. A rule that coherently and feasibly addresses these varied supply chains would have disproportionate economic and supply chain impacts relative to the reduction of national security risks. Further, focusing on the ADS software supply chain appropriately mitigates the national security risks that they present while limiting the supply chain and economic impact. While BIS recognizes that the scope of data captured by connected automotive systems is vast and that multiple systems may pose national security risks, as discussed above, it has decided to focus its current efforts on VCS hardware and covered software. However, BIS does not foreclose the possibility of further addressing other systems, including additional aspects of VCS and ADS, in future regulation. BIS therefore also specifically seeks comment on its determination that VCS and ADS are automotive ICTS integral to Connected Vehicles and pose the greatest and most addressable national security risk, and on its decision to focus this rule on those systems. BIS also specifically seeks comment on whether any risks posed by other connected vehicle ICTS should also be addressed in this rule.

d. Cybersecurity Best Practices

In the ANPRM, the Department requested comments regarding cybersecurity concerns with the connected vehicle supply chain, as well as standards, best practices, and norms that are relied upon and built up by the connected vehicle industry. Commenters largely emphasized that OEMs dedicate significant resources to bolstering the cybersecurity of connected vehicle systems in addition to following or conforming to relevant, established best practices and standards. Some commenters referenced work by vehicle manufacturers to deploy advanced encryption techniques as well as the importance of conducting thorough testing on connected vehicle systems and components, to include penetration testing, fuzz testing, and static code analysis. Others identified specific techniques and best practices,

including role-based access controls. Among the best practices and standards most referenced by commenters were the National Highway Traffic Safety Administration's (NHTSA) Cybersecurity Best Practices for the Safety of Modern Vehicles, International Organization for Standardization's (ISO) and SAE International's standard ISO/SAE 21434, Institute of Electrical and Electronics Engineers Standards Association's (IEEE) standard IEEE 1609.2, SAE J3061, and SAE J3161. At the international level, commenters also referenced the United Nations Economic Commission for Europe (UNECE) Regulations 155 (R155) and R156, which address whole-of-vehicle and software update cybersecurity, respectively. One commenter encouraged BIS to pay particular attention to R155 and R156 given the standards' mandatory coverage in UNECE member states and their ability to provide common best practices to vehicle manufacturers globally.

Many commenters underscored that security is a shared responsibility between OEMs and cloud service providers (CSPs), explaining that while CSPs manage the infrastructure layer, CSP customers are responsible for implementing appropriate configurations and controls in the cloud to protect their data. Commenters also emphasized that practices for automotive cloud security and cloud data access vary between OEMs and according to the specific contractual terms between the OEM and CSP. Some submissions pointed to ISO's and International Electrotechnical Commission's (IEC) standard ISO/IEC 27001 and third-party certifications and attestations, such as the Cloud Security Alliance Cloud Controls Matrix, as models for cloud security best practices and standards. With regard to electric vehicle charging infrastructure, commenters pointed to ISO 15118, National Institute of Standards and Technology's (NIST) Internal Report (IR) 8473, and German technical specification DIN 70121, but they emphasized that specific practices vary according to OEM due to differing battery types and configurations.

BIS acknowledges that cybersecurity standards and best practices, particularly many of those mentioned in submissions, serve a crucial function in promoting the safety and security of vehicles. While BIS generally encourages the use of cyber security standards and best practices, BIS also acknowledges that no standard BIS is aware of or that was identified in comments—either currently in effect or under development—would sufficiently

mitigate the undue or unacceptable risks posed by foreign adversary involvement in connected vehicle ICTS supply chains as described in this proposed rule, even if widely adopted by industry. The standards and guidance BIS reviewed are primarily focused on hardening automotive systems from external access. Standards and guidance alone are insufficient to address risks from within the supply chain, as the systems are not, and cannot be hardened against the OEM or tier 1 and 2 suppliers that have or maintain privileged access to them. As a result, BIS is not proposing to adopt cybersecurity standards and best practices as part of the rule but may consider the scope and nature of their adoption on a case-by-case basis as part of the Specific Authorizations process described in greater detail below.

e. Authorizations and Mitigations

In the ANPRM, BIS sought comment on processes and mechanisms that BIS could implement to authorize an otherwise prohibited transaction with the adoption of mitigation measures. Commenters were generally aligned regarding authorizations and potential mitigation schemes. Several commenters requested that BIS adopt (1) an advisory opinion program for connected vehicles; (2) a trusted trader program to simplify compliance and avoid the complexity and uncertainty associated with a licensing regime; and (3) a program allowing OEMs and suppliers to self-certify compliance with the regulation. BIS has considered each of the comments in full and is proposing an advisory opinion program; procedures for VCS hardware importers and connected vehicle manufacturers to submit Declarations of Conformity, which allow OEMs and suppliers to self-certify their compliance with the regulation; as well as procedures for VCS hardware importers and connected vehicle manufacturers to determine eligibility for a General Authorization or apply for a Specific Authorization. BIS is not proposing a trusted trader program at this time because of the complexity, scale, and opacity of existing connected vehicle supply chains, but may consider establishing such a program to facilitate compliance as supply chains evolve and welcomes comment on such a program as well as any other alternate compliance mechanisms.

A significant portion of commenters raised and rejected data localization requirements as a potential solution to the data exfiltration concerns associated with connected vehicles. Instead, many argued that data exfiltration concerns

could instead be mitigated by securing a demonstrated commitment to privacy and security from OEMs and suppliers, primarily through the adoption of industry cybersecurity best practices and standards. Some commenters also pointed to company membership in the Automotive Information Sharing and Analysis Center (Auto-ISAC) as another method for entities to demonstrate commitment to cybersecurity best practices. As discussed above, BIS has opted not to require adherence to any specific standard or best practice as a prerequisite to securing an authorization to engage in an otherwise prohibited transaction, but BIS reserves the right to consider compliance with them on a case-by-case basis in conjunction with other potential mitigations.

f. Economic Impacts

Comments generally agreed that prohibitions affecting a major supplier of a component used in Connected Vehicles could result in negative economic outcomes. Commenters raised several concerns, including increased manufacturing costs for U.S. auto manufacturers that would likely be passed onto consumers; a decline in long-term U.S. competitiveness vis-à-vis foreign auto manufacturers; disincentivizing further investment in connected vehicles and autonomous vehicle research and development (R&D), potentially reducing future employment in the U.S. auto industry; and a decline in the safety and quality of connected vehicles available to U.S. consumers. Several commenters also noted that regulation may have an outsized impact on small businesses, which often lack the due diligence and compliance resources of their larger competitors. To mitigate these outcomes, several commenters requested substantial lead time for manufacturers to identify and source from alternative suppliers. Lastly, multiple submissions emphasized that not all components in connected vehicles produced by entities owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary necessarily pose a cybersecurity or national security risk, especially for components with minimal or no connectivity capability.

Following consideration of these comments, BIS proposes to allow (1) until Model Year 2027, for connected vehicle manufacturers to come into compliance for transactions involving covered software, (2) until model year 2030, or January 1, 2029, for VCS hardware importers to come into compliance for transactions involving VCS hardware; and (3) until model year

2027 for connected vehicle manufacturers that are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia to sell connected vehicles with VCS hardware and/or covered software. Moreover, to address concerns about the resources small businesses are able to devote to compliance, BIS is proposing a general authorization that would permit certain small businesses to engage in otherwise prohibited transactions. BIS also emphasizes that this rule would narrowly target the specific automotive systems that pose the greatest risk when designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of certain foreign adversaries. As such, the rule would not broadly prohibit the import of connected vehicle technologies from foreign adversary nations, nor would it require market participants to alter supply chains for low-risk or unconnected components.

BIS believes that the implementation timeline strikes an appropriate balance between minimizing significant disruptions to the connected vehicles supply chain and mitigating the national security risk posed by foreign adversary involvement in the connected vehicles supply chain. Given the relatively limited amount of foreign adversary linked hardware and software in U.S. vehicles today, the software prohibitions proposed in this rule would address the most immediate threats to U.S. national security while allowing industry time to come into compliance with the prohibitions on VCS Hardware.

IV. Risks Associated With Vehicle Connectivity Systems and Automated Driving Systems When Designed, Developed, Manufactured, or Supplied by Persons Owned by, Controlled by, or Subject to the Jurisdiction or Direction of the PRC and Russia

Following consideration of comments received on the ANPRM, and further consideration of the risks and vulnerabilities associated with various ICTS components that are critical to the operation of CVs, BIS proposes to focus its rule on two integral ICTS systems—VCS and ADS—when designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of two foreign adversary entities—the PRC and Russia. Below, BIS further explains its understanding of the undue and unacceptable risks associated with these particular systems, and these particular foreign adversaries, and seeks public comment on the systems and foreign

adversaries addressed in the proposed rule.

a. Vulnerabilities Associated With Vehicle Connectivity Systems and Automated Driving Systems

1. Vehicle Connectivity Systems

The term VCS encompasses hardware and software systems—such as the telematics control unit (TCU), cellular modems and antennas, and other automotive components—that integrate various radio frequency communication technologies and enable Connected Vehicles to access external data sources, facilitate vehicle-to-vehicle communication, and provide enhanced services to users through seamless connectivity options. For example, as the primary automotive VCS component, a TCU acts as the primary interface between the internal network and external communication channels. It collects data from onboard sensors such as GPS, accelerometers, gyroscopes, BMS, and other ECUs via wired networks like CAN bus, LIN, FlexRay, Automotive Ethernet, K-Line, as well as wireless protocols such as Bluetooth and Wi-Fi. Some systems use cameras and microphones to facilitate facial recognition of drivers, or to respond to voice commands of drivers. Once gathered, the TCU converts this internal data into radio frequency signals suitable for transmission over the chosen wireless protocol. In other words, as the vast array of sensors on a connected vehicle collect information about a driver's location, speed, voice patterns, battery state of charge, or other vehicle diagnostic and operational information, the TCU converts that data into a format that can be transmitted to systems outside the vehicle and then enables that transmission.

While the increased degree of vehicle connectivity offers benefits to both consumers and manufacturers, it also increases risks to consumers and manufacturers due to the number of access points into the internal vehicle network, each of which may present multiple new software vulnerabilities for adversaries to exploit. See National Renewable Energy Laboratory, "Vehicle Cybersecurity Threats and Mitigation Approaches," (Aug. 2019), <https://www.nrel.gov/docs/fy19osti/74247.pdf>. Such compromise of VCS software could occur at various points of the software development lifecycle, including tool development, source code repositories, open-source dependencies, software updates, and shipment interdiction. For instance, Upstream's 2024 Global Automotive Cybersecurity Report documented a case

where security researchers installed malicious software on the VCS by performing a simulated jailbreak attack of an OEM's VCS using a voltage fault injection on the chip-maker's processor. This malicious software unlocked vehicle manipulating features such as acceleration and heated seats, provided access to private user data such as a user's phonebook and calendar entries, and enabled decryption of encrypted Non-Volatile Memory Express (NVMe) storage, manipulation of the car's identity, and extraction of the vehicle-unique credential used for authenticating and authorizing the OEM's internal service network. *See Upstream, 2024 Global Automotive Cybersecurity Report* (Feb. 2024), <https://upstream.auto/reports/global-automotive-cybersecurity-report/>. By compromising software or its dependencies, malign actors may surveil, disrupt, damage, or otherwise exploit the data or systems of those who use the software. *See National Counterintelligence and Security Center, "Software Supply Chain Attacks,"* (Mar. 2021), https://www.dni.gov/files/NCSC/documents/supplychain/Software_Supply_Chain_Attacks.pdf.

The threat of such a cyber operation by malicious actors can grow significantly when firmware or hardware components are intentionally designed with vulnerabilities. Access to the hardware supply chain for VCS provides an avenue for threat actors to manipulate or insert, with malicious intent, hardware, or firmware modules into telematics hardware components such as modems, Systems on Chip (SoC), Printed Circuit Boards (PCB), central processing units, and antennae. Manipulating or modifying hardware and associated firmware in the supply chain could also allow foreign adversaries to insert a backdoor, granting them control over the VCS. *See Cybersecurity and Infrastructure Security Agency, Defending Against Software Supply Chain Attacks* (April 2021), https://www.cisa.gov/sites/default/files/publications/defending_against_software_supply_chain_attacks_508.pdf, and National Counterintelligence and Security Center, "Software Supply Chain Attacks," (Apr. 2023), <https://www.dni.gov/files/NCSC/documents/supplychain/Software-Supply-Chain-Attacks.pdf>. For instance, cellular and satellite telecommunications transceivers are pivotal connectivity components in the VCS, utilizing radio frequency (RF) energy to facilitate the transmission and reception of data

between a vehicle and the external world. If these transceivers are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, such actors would have the means and capability to introduce vulnerabilities that could be exploited to intercept and/or compromise the information exchanged between the connected vehicle and the external world.

2. Automated Driving Systems

The complexity of ADS software, the large foundation of data sources, and the driving responsibilities inherent to ADS render it a valuable target for exploitation. An ADS encompasses the upper end of the spectrum of autonomy levels that dictate the vehicle's independence and the extent of driver intervention required. As defined by the SAE J3016, autonomy levels range from Level 0 (no automation) where the driver controls all aspects of driving, to Level 5 (full automation) where the vehicle can operate independently under all conditions without human intervention. Levels 1 and 2 offer driver assistance through systems that control either steering or acceleration and braking, while Levels 3 through 5 (which generally comprise ADS) progressively increase the system's responsibility for driving tasks, with Level 4 requiring the ability to complete all driving functions within defined operational design domains (ODDs). As the autonomy level increases, the reliability and safety of the ADS become increasingly reliant on the system's operational performance, safety protocols, and cybersecurity measures. *See Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles*, SAE International, (Apr. 2021), https://www.sae.org/standards/content/j3016_202104/.

An ADS must be able to execute Dynamic Driving Tasks (DDTs) within specific ODDs. DDTs include critical tasks such as steering, braking, acceleration, and Object and Event Detection, Classification and Response (OEDR). OEDR enables an ADS to perceive and respond to surrounding objects and events, a responsibility that shifts progressively from the driver to the ADS itself as the degree of vehicle autonomy increases. *See Edward Griffor, David Wollman, and Christopher Greer "Automated Driving System Safety Measures Part 1: Operating Envelope Specification," NIST Special Publication 1900-301* (2021), <https://nvlpubs.nist.gov/>

[nistpubs/SpecialPublications/NIST.SP.1900-301.pdf](https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1900-301.pdf).

An ADS relies on a large foundation of connected information sources for decisions and outputs which in turn could create inherent vulnerabilities. As a result, the complex software systems that drive decisions for an ADS are valuable targets for malicious actors to exploit. Software-based threats to Connected Vehicles equipped with an ADS include manipulation of sensors to create phantom objects; manipulation of ADS software to detect, capture, and retain information about specific geographic areas or other sensitive data; or other manipulation of sensor fusion processing software that could lead to faulty and dangerous vehicle decision making, to include unauthorized control over the Connected Vehicle. *See National Counterintelligence and Security Center, "Autonomous Automotive Vehicle Supply Chain Risk,"* (2022), <https://www.dni.gov/files/NCSC/documents/supplychain/autonomous-vehicles-placemat-2022-D9A54B50-.pdf>.

A compromised ADS creates opportunities for data exfiltration and unauthorized vehicle manipulation due to the direct access it has to the internal vehicle network (IVN). The IVN controls the communication framework within a Connected Vehicle, overseeing the ECUs responsible for engine control, traction control, door locks, climate control, battery management, powertrain, airbags, cameras, and radar functionalities. These ECUs also communicate via overlaid communication networking protocols such as a CAN bus, Local Interconnect Network (LIN), and ethernet. *See Anastasios Giannaros, et al. "Autonomous Vehicles: Sophisticated Attacks, Safety Issues, Challenges, Open Topics, Blockchain and Future Directions," Journal of Cybersecurity and Privacy* 3.3 (2023). Because ADS interacts with ECUs through the IVN, a compromised ADS has the capability to execute functions that affect nearly all of a Connected Vehicle's software and hardware components. For example, an update to an ADS could alter the outputs the ADS makes to a body control unit, enabling the ADS to erroneously and dangerously open a vehicle's door while in motion. Moreover, because many Connected Vehicles maintain their own networks and actively scan their operating environment for other proximate networks, an ADS can also potentially be used to impact the IVN of other vehicles or transportation infrastructure networks through vehicle-to-vehicle communication. *See National*

Counterintelligence and Security Center, *Autonomous Automotive Vehicle Supply Chain Risk*, (Apr. 2022), <https://www.dni.gov/files/NCSC/documents/supplychain/autonomous-vehicles-placemat-2022-D9A54B50-.pdf>, and Patrick Wagner, Nikolai Puch, and David Emeis, “Cybersecurity risk analysis of an automated driving system,” *Fraunhofer Institute AISEC*, (Oct. 2023), <https://publica.fraunhofer.de/entities/publication/4d66e81e-3570-4c49-9f8c-8c9967a34ca6/details>.

Given the significant processing power and complex decision-making ability of an ADS, the risks arising from ADS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary extend beyond the IVN itself and can include risks to the fidelity and integrity of data that flows to downstream or adjacent transportation infrastructure. Foreign adversaries can corrupt ADS data by exploiting existing vulnerabilities in ADS connectivity environments (see section IV(b) below). As such, direct access to an ADS afforded to a malicious actor through the design, development, manufacture, or supply of ADS software has the potential to cause severe adverse consequences to U.S. national security and U.S. persons.

b. Threats Associated With the PRC and Russia

The design, development, manufacture, or supply of certain VCS and ADS components by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia poses undue or unacceptable risks to national security and U.S. persons. The PRC and Russia have adopted political, legal, and regulatory regimes that enable their governments to exercise direct and indirect ownership, control, or influence over entities in the connected vehicle supply chain. Unlike other foreign adversaries, the PRC and Russia also have certain current and anticipated industrial capabilities and expertise that uniquely position them within the global automotive market to pose an outsized risk, particularly when paired with the vulnerabilities present within certain connected vehicle systems.

1. PRC

The PRC's role in the U.S. connected vehicle supply chain presents undue and unacceptable risks. The PRC has a large and growing automotive sector

with strong connections to non-PRC, including U.S., automakers providing it potential increased access to the U.S. automotive market. Further, the PRC's automotive sector has historical and ongoing links to the PRC military and is influenced by pervasive government intervention, including through legal and regulatory structures that increase government oversight of and control over PRC-based companies and their foreign subsidiaries. See Du Xiaoying and Wang Siyi, “Dongfeng plays pivotal role in supporting China's military,” *China Daily*, (Sept. 25, 2015), https://www.chinadaily.com.cn/cndy/2015-09/25/content_21976945.htm, and Matthew Funaiolo et al., “China Accelerates Construction of ‘Ro-Ro’ Vessels, with Potential Military Implications,” Center for Strategic and International Studies, (Oct. 2023), <https://chinapower.csis.org/analysis/china-construct-ro-ro-vessels-military-implications/>. Moreover, the PRC possesses advanced cyber espionage capacities that it exercises through both state and non-state cyber actors exacerbating such risks.

First, the size and scale of state control in the PRC auto sector poses outsized risks, increasing the vectors by which the national security threats associated with Connected Vehicles can enter the United States. The PRC automotive sector has played an important role in its domestic industrial policy since 1986, when the sector was first named a “pillar industry” in the Seventh Five-Year Plan. The Fourteenth Five-Year Plan, the latest strategic framework for the PRC, continues to prioritize the technology innovation and sustainable development of the automobile market, including new energy vehicles and connected vehicle software and hardware systems. See Ben Murphy, “Outline of the People's Republic of China 14th Five-Year Plan for National Economic and Social Development and Long-Range Objectives for 2035,” Center for Security and Emerging Technology, (May 2021), https://cset.georgetown.edu/wp-content/uploads/t0284_14th_Five_Year_Plan_EN.pdf. For many years, the state has pursued a number of policies and practices to further its industrial policy objectives in the automotive sector, including mandatory joint venture requirements, foreign equity restrictions, massive subsidies and other financial support measures, and various other preferences and discriminatory policies and practices. The PRC automotive sector's growth was also led in part by several prominent state-

owned firms that began as military equipment suppliers (e.g., Chang'an Automobile, Changhe, Hunan Changfeng Motor) or have since risen to become prominent state-owned firms (e.g., GAC Group, Chery Automobile Co.). See Mattias Holweg, Jianxi Luo, and Nick Oliver, *The past, present and future of China's automotive industry: a value chain perspective*, *International Journal of Technological Learning, Innovation and Development* 2 (Feb. 2009), <https://www.pure.ed.ac.uk/ws/portalfiles/portal/7765689/Oliver.pdf>. In recent years, this growth and development has led to a massive surge in domestic vehicle production, with Chinese vehicle production increasing by 1.5 times over the 15-year span between 2008 and 2023. Indeed, in 2023, the PRC alone was responsible for nearly 33 percent of global passenger vehicle production. See VDA, *Global passenger vehicle production in 2023, by country [Graph]*, (Retrieved July 23, 2024), <https://www.statista.com/statistics/277055/global-market-share-of-regions-on-auto-production/>, and OICA & Statista, *China's share in global vehicle production from 2008 to 2021 [Graph]*, (Mar. 17, 2022), <https://www.statista.com/statistics/233942/chinas-share-of-global-production-capacity-of-the-automobile-industry/>. Amid this significant growth in the PRC's domestic auto industry, Chinese automakers, both state-owned and private firms, have leveraged their significant state-backed support, including subsidies, to fuel a global expansion that has seen Chinese automakers establishing foreign operations in countries like South Africa, the Netherlands, Thailand, Japan, and Brazil, among others, increasing the risks stemming from PRC auto manufacturing in third countries. This expansion, combined with recent investment announcements, has spurred concerns that Chinese automakers may soon seek to further expand into the United States either through exports or the establishment of additional manufacturing facilities. Some PRC-based companies have announced plans to establish manufacturing facilities in Mexico, which could enable them to receive favorable trade terms contained in the U.S.-Mexico-Canada Agreement (USMCA). Such a significant position within the global auto sector greatly expands the number of potential nexus points between PRC connected vehicle suppliers and U.S. automakers and U.S. consumers, including indirectly through auto manufacturers in third countries.

Second, the military linkage between the PRC government and the automotive sector continues to the current day with the PRC's military-civil fusion strategy—which seeks to, among other goals, exploit investment and innovation within the PRC's private sector to achieve military modernization goals—and has prioritized specific information and communication technologies that are integral to connected vehicle supply chains (e.g., telecommunications, artificial intelligence). See Ben Murphy, “Outline of the People's Republic of China 14th Five-Year Plan for National Economic and Social Development and Long-Range Objectives for 2035,” Center for Security and Emerging Technology (May 2021), https://cset.georgetown.edu/wp-content/uploads/t0284_14th_Five-Year_Plan_EN.pdf. Strategies to achieve these goals include mandating collaboration between PRC-based companies and the military and establishing public and private firms as vectors to facilitate technology transfer, industrial espionage, and intellectual property theft that would be advantageous for the PRC military. See Office of the Dir. of Nat'l Intelligence, *Annual Threat Assessment of the U.S. Intelligence Community*, (Feb. 6, 2023), <https://www.odni.gov/files/ODNI/documents/assessments/ATA-2023-Unclassified-Report.pdf>.

Third, even beyond military-civil fusion, the role of the PRC government in the auto sector has only grown as government intervention in the market increases, including through direct ownership of prominent industry participants, the purchasing of so-called “golden shares” to gain significant levels of influence within otherwise private firms, embedding Chinese Communist Party (CCP) representatives within corporate boards and management, and the forceful application, or threat thereof, of the PRC's expanding security laws, including its digital era legal structure. See Lingling Wei, “China's New Way to Control Its Biggest Companies: Golden Shares,” *Wall Street Journal* (Mar. 2023), <https://www.wsj.com/articles/xi-jinpings-subtle-strategy-to-control-chinas-biggest-companies-ad001a63>. Laws promulgated in recent years provide the PRC government increased oversight and control over PRC-based companies and their foreign subsidiaries, providing a lever for influence over corporate operations that further exacerbates the threat that the PRC poses to U.S. national security. These laws require PRC-based

companies, wherever located, to comply with certain access and information requests upon demand from the PRC, and therefore could be used by the PRC to obtain business or other data from PRC-based companies involved in the connected vehicle supply chain. Companies operating under these laws frequently highlight the lack of transparency, consistency, clarity, and predictability of the enforcement of these laws, publicly stating that PRC laws relating to cybersecurity, data storage, or cryptography are not subject to the same degree of judicial accountability as they might be in other jurisdictions. In particular, BIS notes the PRC may utilize a suite of national security laws (e.g., *Counter-Espionage Law of the People's Republic of China* [promulgated by the Standing Committee of the National People's Congress, Nov. 1, 2014, amended Apr. 26, 2023, effective July 1, 2023]; *National Security Law of the People's Republic of China* [promulgated by the Standing Committee of the National People's Congress, July 1, 2015, effective July 1, 2015]; *National Intelligence Law of the People's Republic of China* [promulgated by the Standing Committee of the National People's Congress, June 27, 2017, effective June 28, 2017, amended Apr. 27, 2018]; *Anti-Terrorism Law of the People's Republic of China* [promulgated by the Standing Committee of the National People's Congress, Dec. 27, 2015, effective Jan. 1, 2016, amended Apr. 27, 2018]) to compel companies, including those in the connected vehicle supply chain, to support national security efforts—which are more broadly defined in the PRC than in the United States—or military agents upon request, including in some cases through the creation of backdoors and security vulnerabilities in products sold abroad, and in many cases, the PRC prohibits companies from disclosing that such a request was made. See U.S. Department of Homeland Security, “Data Security Business Advisory: Risks and Considerations for Businesses Using Data Services and Equipment from Firms Linked to the People's Republic of China,” (Dec. 2022), https://www.dhs.gov/sites/default/files/publications/20_1222_data-security-business-advisory.pdf. Additionally, PRC authorities have established a regulatory system that effectively allows them to stockpile cyber vulnerabilities. Entities subject to these regulations, including automotive systems manufacturers, are required to report vulnerabilities upon discovery to PRC authorities before patching them. See Cyberspace Administration of China,

“*Provisions on the Management of Security Vulnerabilities of Network Products*,” (Jul. 2021), https://www.cac.gov.cn/2021-07/13/c_1627761607640342.htm. This requirement drastically increases the ability of the PRC government and PRC-backed cyber actors to take action against the United States using connected hardware and its associated software by creating an accessible library of known and potentially unpatched vulnerabilities. And fourth, the PRC has demonstrated a high level of competency in cyber malfeasance. The recent Volt Typhoon action exemplified how PRC cyber actors preposition themselves across U.S. critical infrastructure and military assets in order to, at a potential future date, launch an attack and impede U.S. decision making, induce social panic, and interfere with the deployment of U.S. military forces. See Cybersecurity and Infrastructure Security Agency, “PRC State-Sponsored Actors Compromise and Maintain Persistent Access to U.S. Critical Infrastructure,” (Feb. 2024), <https://www.cisa.gov/news-events/cybersecurity-advisories/aa24-038a>. A 2022 Annual Report to Congress by the U.S.-China Economic and Security Review Commission found that the PRC's ability and willingness to “weaponize” its own industries, particularly its cybersecurity industry, grants the country an asymmetric advantage over the United States; an argument that was further supported in reporting earlier this year that detailed the methods by which known government-affiliated cyber threat groups utilize private firms to carry out their attacks. See U.S.-China Economic and Security Review Commission, “2022 Annual Report to Congress,” (Nov. 2022), https://www.uscc.gov/sites/default/files/2022-11/2022_Annual_Report_to_Congress.pdf; Christian Shepherd et al., “Leaked files from Chinese firms show vast international hacking efforts,” *The Washington Post* (Feb. 22, 2024), <https://www.washingtonpost.com/world/2024/02/21/china-hacking-leak-documents-isoan/>. Additionally, a 2012 report from United States Senate Permanent Select Committee on Intelligence examining the national security risks posed by the PRC-based companies Huawei and ZTE specifically argued that there are numerous opportunities for PRC-based threat actors to insert malicious hardware or software components into ICTS products throughout the product development stage. See Permanent Select Committee on Intelligence, “*Investigative Report on the U.S.*

National Security Issues Posed by Chinese Telecommunications Companies Huawei and ZTE" (Oct. 2012), [https://intelligence.house.gov/sites/intelligence.house.gov/files/documents/huawei-zte%20investigative%20report%20\(final\).pdf](https://intelligence.house.gov/sites/intelligence.house.gov/files/documents/huawei-zte%20investigative%20report%20(final).pdf). This risk has not diminished, as indicated by a study of designed vulnerabilities in products conducted by the Georgetown Security Studies Review, which outlines five years of persistent insertion of malicious code by PRC-based threat actors. See Georgetown Security Studies Review, "Flawed by design electronics with pre-installed malware" (May 2018), <https://georgetownsecuritystudiesreview.org/2018/05/23/flawed-by-design-electronics-with-pre-installed-malware/>. Given the above, the PRC's access to the U.S. connected vehicle supply chain through its growing automotive sector, military-civil fusion and other corporate governance policies, and legal institutions paired with its development of mature cyber espionage capabilities have increased the risk that the PRC could alter the systems in, or obtain and manipulate information to or about, market participants who use connected vehicle ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC.

2. Russia

The Russian state has prioritized the growth of its automotive manufacturing industry, instituted a legal and regulatory framework to compel company data sharing with the state, and maintained a long history of malicious cyber operations against the U.S. Under these circumstances, there is an increasing likelihood that Russia emerges as a supplier of connected vehicles technologies for the U.S. market, providing the Russian government a means of exploiting U.S. connected vehicles. Moreover, incorporating Russian hardware or software into the U.S. connected vehicle supply chain poses undue and unacceptable risks to U.S. critical infrastructure and U.S. persons.

First, while Russia has historically been less active in the global automotive sector than the PRC, the Russian government has recently sought to revitalize its own domestic auto manufacturing industry following the exodus of foreign automakers after the imposition of significant additional sanctions in 2022. In 2024 alone, the Russian auto market is projected to experience a 15 percent increase in passenger vehicle sales, marking a noted uptick since the market crashed

following sanctions and some Russian auto manufacturers have continued introducing new models even amid broader economic headwinds. See Reuters, "Russia's 2024 car sales forecast raised to 1.45 mln units, AEB says," (Jul. 2024), <https://www.reuters.com/business/autos-transportation/russias-2024-car-sales-forecast-raised-145-mln-units-aeb-says-2024-07-03>. The void left by many foreign firms has made Russia a valuable export market for Chinese auto manufacturers seeking to expand their presence globally with some Chinese auto brands seizing significant market share from Russian competitors accounting for almost 56 percent of domestic auto sales in August 2023. See Gleb Stolyarov and Alexander Marrow, "Exclusive: Chinese car sales boom in Russia levels off amid shaky local recovery," *Reuters* (Nov. 2023), <https://www.reuters.com/business/autos-transportation/chinese-car-sales-boom-russia-levels-off-amid-shaky-local-recovery-2023-11-24/>. In Russia, the revitalization of the domestic economy, in particular the domestic auto sector, has become a key focus of the government since the imposition of sanctions in recent years. The Russian government has released several plans pointing to a prioritization of the development of its domestic automotive market with a particular focus on research and development for new technology, including autonomous vehicles and V2X vehicle connectivity systems. See Russian Federation, *Order of the Government of the Russian Federation of December 28, 2022 No. 4261-r On Approval of the Strategy for the Development of the Automotive Industry of the Russian Federation until 2035* (Jan. 4, 2023), <https://www.garant.ru/products/ipo/prime/doc/405963861/#1000> and See Russian Federation, *Order of the Government of the Russian Federation of August 23, 2021 No. 2290-r On Approval of the Concept for the Development of Electric Vehicle Production and the Transport Strategy of 2030*, (2023), <http://static.government.ru/media/files/bW9wGZ2rDs3BkeZHf7ZsaxnIbJzQbJf.pdf>. The development of these interlocking national transportation and automotive industry strategies involved stakeholders from domestic automakers, technology sectors, and the Russian government, illustrating a coordinated effort across the Russian state and its domestic automotive industry. In order to extend the reach of the state into the Russian auto industry, in February 2024, Russia established a state-owned corporation named Rosavto that will act

as liaison between government and industry and will develop production plans for vehicles and automotive spare parts, oversee the development of new models and technologies, and manage order distribution, legislative initiatives, and workforce training. See Eugene Gerden, "New State Corporation to Oversee Russian Auto Industry," *Wards Auto* (Feb. 2024), <https://www.wardsauto.com/regulatory/new-state-corporation-to-oversee-russian-auto-industry>. Concerted efforts by the Russian government to grow the domestic Russian automotive industry increase the likelihood that Russian-manufactured VCS hardware or covered software will enter the U.S. connected vehicle supply chain, which, as described below, would present an undue or unacceptable risk to U.S. national security.

Second, like the PRC, the Russian government employs a suite of laws that enable it to compel domestic companies with overseas operations to provide data gleaned through foreign ventures or to surrender similar operational assets to the Russian state. These laws (e.g., Russian Law Federal Security Service No. 40-FZ, "Operational-Investigative Activity" No. 144-FZ, 2014 Amdt. to No. 97-FZ) provide the Russian government direct control over Russian corporations' activities and facilities, including data or customer information, and mandate that companies cooperate with assisting counterintelligence actions as requested by the state, including the Federal Security Service of the Russian Federation (FSB). The FSB can, in some cases, mandate that companies allow the FSB to install equipment on their infrastructure or collect data. Firms that are required to facilitate this surveillance or intrusion activity can also be required to actively obfuscate such requests and must provide the state with any information essential to the decryption of any communications captured. Together, these laws enable the Russian state to collect and exploit sensitive data on or about U.S. persons via Russian businesses and, should Russian companies become more prominent in the connected vehicle supply chain, create a pathway by which the Russian government could secure wide-ranging access to the vast amounts of data collected and processed by Connected Vehicles in the United States. See internet Governance, "Report of Peter B. Maggs," (Dec. 2017), <https://www.internetgovernance.org/wp-content/uploads/12-7-Exhibit-AR-Part-6-Maggs-report.pdf>. Public reports have consistently raised concerns about

Russian government laws concerning data collection, citing a lack of appropriate safeguards to prevent misuse, to include judicial or public oversight. More broadly, reports have repeatedly documented the uneven application of the rule of law, lack of judicial accountability, recurrent violations of judicial proceedings, and challenges with judicial independence. See Justin Sherman, “Russia is weaponizing its data laws against foreign organizations,” Brookings, (Sept. 2022), <https://www.brookings.edu/articles/russia-is-weaponizing-its-data-laws-against-foreign-organizations/>; Evgeni Moyakine and A. Tabachnik, “Struggling to strike the right balance between interests at stake: The ‘Yarovaya’, ‘Fake news’ and ‘Disrespect’ laws as examples of ill-conceived legislation in the age of modern technology,” *Computer Law & Security Review* 40, (Apr. 2021), <https://www.sciencedirect.com/science/article/pii/S0267364920301175>.

Third, apart from the access codified in Russia’s legal framework, the country has a longstanding pattern of utilizing cyber operations to gain illicit access to systems that advance the strategic ends of Russian authorities. For example, in December 2020 the company SolarWinds announced it was the target of a two-year-long cyber operation perpetrated by Russian hackers in the Russian Foreign Intelligence Services (SVR). See U.S. Securities and Exchange Commission, “SEC Charges SolarWinds and Chief Information Security Officer with Fraud, Internal Control Failures,” (Oct. 2023), <https://www.sec.gov/newsroom/press-releases/2023-227>. The perpetrators of the SolarWinds supply chain attack used a software update to deliver its malware to the platform’s users after Russian intelligence services obtained covert access to the computer systems on which the platform was installed and ultimately impacted more than 18,000 users, including more than 100 companies and nine U.S. Government agencies. This attack credibly demonstrates how Russian actors can infiltrate global enterprise systems via software updates and exemplifies how they could similarly leverage software as a means to exploit connected vehicles in the United States. Additionally, a 2023 Cyber Security Advisory suggests that exploitation of information technology firms and their software will continue to be a persistent tactic leveraged by the Russian government to collect intelligence. See Joint Cyber Security Advisory, “Russian Foreign Intelligence Service (SVR) Exploiting JetBrains TeamCity CVE

Globally” (Dec. 2023), <https://www.cisa.gov/news-events/cybersecurity-advisories/aa23-347a>. BIS has further identified Kaspersky Lab as an example of how Russia has leveraged software companies to give it the ability to collect and weaponize the personal information of Americans. See Bureau of Industry and Security, “Final Determination: Case No. ICTS–2021–002, Kaspersky Lab, Inc.” (Jun. 2024), <https://www.federalregister.gov/documents/2024/06/24/2024-13532/final-determination-case-no-icts-2021-002-kaspersky-lab-inc>. These political, legal, and regulatory frameworks, combined with the PRC’s and Russia’s demonstrated capability to exploit ICTS supply chains through malicious cyber activity, exacerbate BIS’s concern that the threats posed by these foreign adversaries could be directed at the U.S. connected vehicle supply chain, including integral systems such as VCS and ADS. The persistent connectivity and software-driven capabilities of VCS and ADS, combined with the vast amounts of data that traverse these systems, make them valuable and likely targets for the PRC and Russian governments to compromise.

c. Consequences

Taken together, VCS and ADS designed, developed, manufactured, or supplied by persons under the ownership, control, jurisdiction, or direction of the PRC or Russia manifest undue and unacceptable risks to United States national security in several ways. If left unaddressed, the interaction of threats and vulnerabilities could result in the exfiltration of sensitive U.S. persons’ data to foreign adversaries or the remote or automated manipulation of Connected Vehicles by the PRC and Russia, among other concerns.

First, the integration of compromised VCS or ADS into a completed vehicle could undermine the reliability of a connected vehicle or its underlying control systems. Compromised components in VCS or ADS could result in increased frequency and severity of connected vehicle malfunctions that could in turn detrimentally impact U.S. national security, including the resiliency of U.S. critical infrastructure, or the safety of U.S. persons.

Given the persistent connectivity of VCS and ADS and the essential functions that they service in the operation of Connected Vehicles, these systems, if compromised and co-opted by an adversary, could serve as a node through which a foreign actor could probe or breach broader ICTS systems within the United States. According to research by Upstream, remote malicious

cyber activities—which rely on network connectivity (e.g., Wi-Fi, Bluetooth, 3/4/5G networks)—have increased significantly in recent years and consistently outnumber malicious cyber activities carried out through physical access to devices since at least 2010, accounting for 95 percent of all malicious cyber activities in 2023. See Upstream, *Upstream’s 2024 Global Automotive Cybersecurity Report* (2024), <https://upstream.auto/reports/global-automotive-cybersecurity-report/>. Considering the increasingly sophisticated methodologies employed by foreign adversaries to gain access to critical U.S. cyber infrastructure, compromised VCS and ADS, with their inherent connectivity, would easily present another attack surface for foreign adversaries to exploit. As detailed in the previous analysis of vulnerabilities inherent in VCS, adversaries with access to VCS, such as to telematics systems, could inject malicious code into a vehicle’s operational systems. Additionally, such malware could be developed in such a way as to exploit vehicle connectivity to propagate itself across multiple systems as the vehicle travels and connects to those discrete systems. In this way, not only would the ICTS integral to Connected Vehicles be compromised, but vehicle systems could be exploited to spread malware with the intent of harming all ICTS systems to which a vehicle connects. See Anastasios Giannaros, et al. “Autonomous Vehicles: Sophisticated Attacks, Safety Issues, Challenges, Open Topics, Blockchain and Future Directions,” *Journal of Cybersecurity and Privacy* 3.3 (2023).

Second, as discussed, both VCS and ADS have significant control over and access to critical vehicle functions, including steering, braking, speed control, ignition, and almost all other mechanical functions of the vehicle. Such extensive control over vehicle operations could enable a foreign adversary to use a compromised VCS or ADS component to hamper vehicle functions or even to manipulate a connected vehicle for malicious purposes. As VCS and ADS control or link to integral vehicle functions, a foreign adversary could even exploit compromised VCS or ADS components to impair or disable a connected vehicle while in transit. Disabled, impaired, or otherwise improperly functioning vehicles could result in grave damage or impediment to critical infrastructure within the United States, or in physical harm to U.S. persons. A disabled, impaired, or erratically functioning

Connected Vehicle, or potentially multiple Connected Vehicles all experiencing such problems simultaneously, could result not only in traffic patterns that would effectively block critical transportation arteries, but could cause collisions ultimately damaging transportation features (e.g., roadways, bridges, tunnels) and energy, telecommunications, and similar infrastructure situated near transportation systems. The potential consequences of widespread connected vehicle impairment could be particularly acute if the targets were fleet vehicles operating in support of infrastructure vital to transportation, energy, water, waste, telecommunications, and other essential services.

The risks to the resiliency of critical U.S. infrastructure posed by connected vehicle components designed, developed, manufactured, or supplied by persons that are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia are further compounded by the potential for VCS and ADS to collect data on infrastructure. Advances in VCS and ADS necessitate increasingly cutting-edge sensor suites incorporating radar, LiDAR, camera, sonar, and computer vision to gather information on the surrounding environment for both onboard computing and remote cloud computing to process data in informing vehicle operating decisions. This vast wealth of data, collected over time by multiple vehicles likely contains valuable information such as location data about critical U.S. infrastructure. For example, data gathered from GPS/GNSS systems in a connected vehicle could be cross-referenced and collated with a multitude of other data to produce information about the location, function, and operational trends of various transportation, energy, or other critical infrastructure. A foreign adversary could extract such critical infrastructure data using its control over designers, developers, manufacturers, or suppliers of VCS and ADS components subject to the foreign adversary's ownership, control, jurisdiction, or direction, thereby increasing the risk and precision of attacks on such critical infrastructure.

Finally, given the volume of information collected by vehicles to support VCS and ADS operation, exploitation of these systems could enable an adversary to cull a tremendous amount of data on vehicle movement across the United States. This information could potentially include data generated on or from fleet

vehicles used by emergency response, law enforcement, or the military. This data, and particularly all metadata and derived data that can be drawn from the raw data, can provide considerable insight into fleet size, composition, and capabilities, as well as information on organizational response times and response procedures. Such information would prove valuable to an adversary seeking to disrupt U.S. emergency response operations. Any potential risks to U.S. national security arising from disrupting emergency response activities are further compounded by the potential for an adversary to exploit access to VCS and ADS to leverage the persistent connectivity required for malign operations, including exploits to trigger improper engine shutdown, brake activation, or electrical system deactivation. Any of these actions have serious consequences for U.S. persons' health and safety. The PRC or Russia could use similar methods to target U.S. persons other than institutions, thereby imperiling the safety and security of individual U.S. citizens or residents. VCS and ADS, if corrupted by the producer at the direction of a foreign adversary, could improperly access driver mobile devices to collect, exfiltrate, and exploit personally identifiable information (PII) or even protected health information (PHI). It is also possible that a foreign adversary could use covert access to VCS and ADS to provide false or misleading information to a driver, causing degraded and dangerous vehicle operation conditions. Such tactics could be used either indiscriminately to sow panic and cause disruption, or to intentionally target specific drivers. Additionally, and as noted by the Office of the Director of National Intelligence in the 2024 National Counterintelligence Strategy, foreign adversaries, like the PRC and Russia, view this kind of PII and PHI as particularly valuable as it provides them "not only economic and R&D benefits, but also useful [counterintelligence] information, as hostile intelligence services can use vulnerabilities gleaned from such data to target and blackmail individuals." See The Director of Nat'l Intelligence, *2024 National Counterintelligence Strategy* (Aug. 2024), https://www.dni.gov/files/NCSC/documents/features/NCSC_CI_Strategy-pages-20240730.pdf.

Even when such systems are not subject to compromise, companies owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary, if occupying certain positions within the supply chain, may

potentially legally gain access to their users' personal data. For example, one prominent Chinese auto manufacturer with operations in the United States publicly states in its U.S. privacy policy that the personal data it may collect (e.g., identifiers, customer records information, internet or other electronic network activity information, geolocation information, professional or employment-related information) is only stored in the United States "in principle," but goes on to note that personal data "may be transferred to our headquarters in China" for processing and storage. While the incorporation in the U.S. supply chain of VCS hardware and covered software designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia poses one type of risk, transactions involving VCS hardware and covered software pose a separate risk when the connected vehicle manufacturer is, itself, owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, even when the connected vehicle manufacturer is located in the United States. connected vehicle manufacturers have privileged and direct access to all systems in the vehicle, including the VCS hardware and covered software. Not only are VCS hardware and covered software built to the connected vehicle manufacturers' specifications but prior to the sale of a completed connected vehicle, connected vehicle Manufacturers are able to exercise significant levels of control over that VCS hardware and covered software with little to no external oversight prior to the sale of the completed connected vehicle. Based on the foregoing, BIS assesses that ICTS transactions involving VCS hardware or covered software designed, developed, manufactured, or supplied by persons owned or controlled by, or subject to the jurisdiction or direction of the PRC or Russia—including transactions to supply the VCS hardware or covered software into the United States market as part of the sale of the completed connected vehicle—present undue or unacceptable risks to the national security of the United States within the meaning of E.O. 13873. BIS welcomes comment on the vulnerabilities and risks it has identified.

V. Discussion of the Proposed Rule and Request for Comments

BIS proposes a regulation that would—absent a general or specific authorization otherwise—(1) prohibit VCS hardware importers from knowingly importing into the United

States certain hardware for VCS; (2) prohibit connected vehicle manufacturers from knowingly importing into the United States completed connected vehicles incorporating covered software; (3) prohibit connected vehicle manufacturers from knowingly selling within the United States completed connected vehicles that incorporate covered software; and (4) prohibit connected vehicle manufacturers who are persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia from knowingly selling in the United States completed connected vehicles that incorporate VCS hardware or covered software (collectively, “Prohibited Transactions”). These prohibitions would apply to transactions when such VCS hardware or covered software is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

BIS anticipates that this rule would primarily impact market participants who could be considered VCS Hardware Importers or connected vehicle manufacturers, such as OEMs and importers of completed connected vehicles, as well as Tier 1 and Tier 2 suppliers of VCS Hardware. For these entities, three compliance mechanisms—Declarations of Conformity, general authorizations, and specific authorizations—are available, depending on whether the VCS hardware importer or connected vehicle manufacturer wishes to engage in an otherwise prohibited transaction. Importantly, because VCS hardware importers and connected vehicle manufacturers frequently offer many different types of products, any one of the three mechanisms may not be available for their entire business. Rather, depending on the product, VCS hardware importers and connected vehicle manufacturers could be required to use a combination of these three mechanisms to meet their obligations under the rule.

First, Declarations of Conformity would have to be submitted to BIS by VCS hardware importers and connected vehicle manufacturers who have not engaged in a prohibited transaction, unless otherwise specified. Such VCS hardware importers and connected vehicle manufacturers would, in this Declaration of Conformity, certify, once per calendar year or model year (or whenever material changes occur) to BIS that the submitter has not engaged in a prohibited transaction and provide certain information on the import of

VCS hardware and/or the import or sale of completed connected vehicles.

Second, a general authorization could be available for VCS hardware importers and/or connected vehicle manufacturers seeking to engage in an otherwise prohibited transaction, depending on the circumstances. A general authorization would allow the VCS hardware Importer and/or connected vehicle manufacturer to engage in the otherwise prohibited transaction, without the need to notify or seek approval from BIS. General authorizations would be available only in a narrow set of circumstances in which the conditions of the otherwise prohibited transaction appropriately mitigate the level of risk associated with the particular transaction. Such conditions would include, for example, when VCS hardware is imported from the PRC or Russia solely for testing purposes, or where the completed connected vehicle that incorporates VCS hardware or covered software from the PRC or Russia will be driven on public roads for fewer than 30 calendar days per year. Those availing themselves of a general authorization would be required to continuously monitor their use of the VCS hardware or completed connected vehicles covered by the General Authorization to ensure the authorization still applies. If a change would render the transaction ineligible for a general authorization, such as a change in the vehicle’s use, the VCS hardware importer or connected vehicle manufacturer would be required to apply for a specific authorization and to cease engaging in such transaction unless and until a Specific Authorization is granted. For example, if a completed connected vehicle that incorporates covered software or VCS Hardware that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia is no longer used solely for display, research, or testing, the VCS hardware importer or the connected vehicle manufacturer would be required to seek a specific authorization. Similarly, if the VCS Hardware Importer or connected vehicle manufacturer meets or exceeds total model year production of 1,000 units, or if a completed connected vehicle that incorporates covered software or VCS hardware that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia is to be used on public roadways for 30 or more days in any calendar year, the VCS hardware

importer or connected vehicle manufacturer would be required to seek a specific authorization from BIS.

Lastly, for VCS hardware importers and connected vehicle manufacturers who wish to engage in a prohibited transaction, but do not otherwise qualify for a general authorization, a specific authorization from BIS would be required before they could proceed with the prohibited transaction. A specific authorization would only be available in circumstances where BIS determines, based on the information submitted by the applicant and other collected information, that the otherwise prohibited transaction does not present an undue or unacceptable risk to U.S. national security. However, as a condition of approving the specific authorization, BIS might impose certain requirements and mitigation measures upon the VCS hardware importers and connected vehicles manufacturers seeking to proceed with the prohibited transaction.

VCS hardware importers and connected vehicle manufacturers could appeal to the Under Secretary for Industry and Security (Under Secretary) any decision by BIS to deny an application for a Specific Authorization, suspend or revoke a previously granted specific authorization, or issue a written notification that a VCS hardware importer or connected vehicle manufacturer is ineligible for a general authorization. Further, the regulation would establish a method for VCS hardware importers and connected vehicle Manufacturers to seek guidance from BIS, in the form of advisory opinions, on prospective transactions that may be prohibited. BIS also proposes to establish a process through which BIS may inform VCS hardware importers or connected vehicle manufacturers that certain of their activities could constitute a prohibited transaction.

In proposing this rule, BIS recognizes that Section 203(b) of IEEPA—*i.e.*, the “Berman Amendment”—limits the scope of the authority to regulate or prohibit transactions relating to “information” or “informational materials.” In relevant part, the Berman Amendment states that the “authority granted to the President by this section does not include the authority to regulate or prohibit, directly or indirectly . . . the importation from any country, or the exportation to any country, whether commercial or otherwise, regardless of format or medium of transmission, of any information or informational materials, including but not limited to, publications, films, posters, phonograph

records, photographs, microfilms, microfiche, tapes, compact disks, CD ROMs, artworks, and newswire feeds.” 50 U.S.C. 1702(b)(3). Consistent with the statute’s text and purpose, as demonstrated by legislative history and context, as well as judicial interpretations, BIS understands the phrase “information or informational materials” to refer to expressive materials and mediums that may be carrying such expressive content. See, e.g., *United States v. Amirnazmi*, 645 F.3d 564, 586–87 (3d Cir. 2011). Accordingly, the Berman Amendment prevents BIS from regulating, directly or indirectly, the import or export of expressive materials. It does not, however, prevent BIS from imposing a regulation that is aimed at the functional capabilities of technology.

The proposed rule is consistent with the Berman Amendment. Its purpose is to regulate transactions involving certain hardware and software based on functional capabilities that can be exploited by foreign adversaries, not the exchange of ideas and expression that the Berman Amendment protects. As discussed in Section IV, VCS Hardware and covered software process and transmit data such as geolocation information or systems diagnostics reports, which are used to monitor and control the vehicle’s safe operation, and that a foreign adversary could also manipulate in ways that could impair or disable the vehicle’s function, leading to dangerous outcomes that pose a harm to U.S. national security. Similarly, the functional data collected by Covered Software—such as high-definition mapping data of infrastructure and roadways—would pose serious risks to that critical infrastructure if collected and exploited by a foreign adversary. As a result, BIS has determined that the proposed prohibitions in this rule are consistent with the Berman Amendment, which was intended to protect materials involving the free exchange of ideas from regulation under IEEPA. BIS is considering whether and how to address the term “information or informational materials” within the context of the proposed rule and may consider further changes to the final rule to reflect our interpretation of this term. BIS welcomes comment on this issue.

Each section of the proposed rule is discussed below. BIS invites comments on all aspects of this proposed rule.

a. Definitions

1. Automated Driving System (ADS)

BIS proposes to define “Automated Driving System” to mean hardware and

software that, collectively, are capable of performing the entire dynamic driving task for a completed connected vehicle on a sustained basis, regardless of whether it is limited to a specific ODD. This definition is consistent with the terminology industry uses for systems that operate at certain advanced levels of autonomy. It is also consistent with definitions issued by NHTSA. Specifically, this definition corresponds to automation levels 3, 4, and 5 as defined by SAE International standard J3016.

2. Completed Connected Vehicle

BIS proposes to define “completed connected vehicle” to mean a connected vehicle that requires no further manufacturing operations to perform its intended function. This definition is consistent with definitions issued by NHTSA. Additionally, for the purposes of this proposed definition, the integration of an ADS into a connected vehicle constitutes a manufacturing operation for a Completed Connected Vehicle. BIS intends this caveat to clarify that a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, whose sole manufacturing or assembly operation is integrating ADS into an otherwise Completed Connected Vehicle, would be subject to the prohibitions in the rule and would need to obtain a Specific Authorization before importing or Selling that completed connected vehicle in the United States.

3. Connected Vehicle

BIS proposes to define “connected vehicle” to mean a vehicle driven or drawn by mechanical power and manufactured primarily for use on public streets, roads, and highways, that integrates onboard networked hardware with automotive software systems to communicate via dedicated short-range communication, cellular telecommunications connectivity, satellite communication, or other wireless spectrum connectivity with any other network or device. Vehicles operated only on a rail line are not included in this definition. This definition incorporates the suggestions of commenters to the ANPRM, many of whom requested that the definition of connected vehicle specify the types of vehicles that would be covered.

4. Connected Vehicle Manufacturer

BIS proposes to define a “connected vehicle manufacturer” to mean a U.S. person (1) manufacturing or assembling completed connected vehicles in the United States; and/or (2) importing

completed connected vehicles for Sale in the United States.

5. Covered Software

BIS proposes to define “covered software” to mean the software-based components, in which there is a foreign interest, executed by the primary processing unit of the respective systems that are part of an item that supports the function of VCS or ADS at the vehicle level. covered software does not include firmware, which is characterized as software specifically programmed for a hardware device with a primary purpose of controlling, configuring, and communicating with that hardware device. At a minimum, this definition of covered software would include operating systems such as a real-time operating system (RTOS), and general-purpose operating systems. An example of covered software within the ADS is, if included in the system, the machine learning software that performs the functions of object detection, classification, and decision making.

Covered software does not include open-source software. BIS understands open-source software as software that can be freely used, modified, and distributed by anyone, with both access to the source code and the ability to contribute to the software’s development and improvement. Given these qualities of open-source software, it is not designed, developed, manufactured, or supplied by any attributable entity. Therefore, the inclusion of open-source software as a component of covered software is not subject to prohibition. However, if licensed open-source software is modified to create proprietary enterprise software for a specific use not meant for redistribution, the resulting software could be subject to prohibition if the person modifying the open-source software is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. In addition to other aspects of this proposed rule, BIS specifically seeks comment on this definition.

6. FCC ID Number

BIS proposes to define “FCC ID Number” as the unique alphanumeric code identifying a product subject to certification by the Federal Communications Commission (FCC) composed of a (1) grantee code and (2) product code.

7. Foreign Interest

For the purposes of this rule, BIS is considering “foreign interest,” when used with respect to property, as any

interest in property, of any nature whatsoever, whether direct or indirect, by a non-U.S. person. Under this definition, a foreign interest can include, but is not limited to, an interest through ownership, intellectual property, contract—*e.g.*, ongoing supply commitments such as maintenance, any license agreement related to the use of intellectual property—profit-sharing or fee arrangement, as well as any other cognizable interest. This definition is consistent with the definition of “interest” used in the context of Office of Foreign Asset Control sanctions, which are, in relevant part, also established pursuant to the statutory requirements of IEEPA. *See* 31 CFR Chapter V, *and, e.g.*, 31 CFR 510.313, 535.312.

Consistent with IEEPA, BIS proposes to regulate only transactions involving property in which a foreign country or national thereof has any such interest. A transaction would be subject to the prohibitions in the proposed rule only if it involves ICTS, specifically VCS hardware or covered software, that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. VCS hardware importers and connected vehicle manufacturers wishing to engage in transactions that this rule proposes to prohibit would need to qualify for a general authorization or obtain a specific authorization. In order to provide sufficient visibility into the supply chains of VCS Hardware and covered software including to verify that the transaction does not involve VCS Hardware or covered software that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia (*see* Section V(c) of this notice and proposed Section 791.305), BIS is proposing to require that VCS hardware importers and connected vehicle manufacturers that import VCS hardware, or import or sell completed connected vehicles that contain covered software in which there is any other foreign interest, submit an annual Declaration of Conformity containing relevant details about the import or Sale. BIS seeks comment on this regulatory approach, including the necessity and efficacy of requiring Declarations of Conformity with respect to VCS hardware and covered software in which there is a foreign interest, though not a foreign adversary interest. BIS also seeks comment on the availability and efficacy of any

alternative approach that would require a narrower set of VCS hardware importers and completed connected vehicle manufacturers to submit Declarations of Conformity, while still achieving the goals of the Declaration of Conformity requirement and addressing the declared emergency under Executive Order 13873.

With respect to VCS hardware that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, BIS proposes to regulate the importation of VCS hardware, making VCS hardware importers responsible for compliance.

With respect to Covered Software, based on discussions with connected vehicle manufacturers, automotive suppliers, and other stakeholders, BIS has come to understand that typically, ADS and VCS software are designed or developed to a connected vehicle manufacturer's specifications. ADS and VCS software is frequently designed, developed, or supplied by foreign persons, and those persons frequently retain a legally cognizable interest in the underlying software, even after it has been integrated into the connected vehicle. For example, foreign software developers may earn profits from use of their software; retain data access and sharing rights to the software; or have obligations to maintain and update the software. Such arrangements are among the types of interests that BIS contemplates as giving rise to an obligation to submit a Declaration of Conformity or, if the software designer, developer, or supplier is a person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary, to qualify for a General Authorization or seek a Specific Authorization under the proposed rule. BIS therefore proposes to regulate covered software by regulating the importation or sale of completed connected vehicles, making connected vehicle Manufacturers responsible for compliance. BIS seeks comment on this understanding of foreign interests in covered software as well as other arrangements in which foreign designers, developers, or suppliers of covered software retain a cognizable legal interest in the software after it is integrated into a connected vehicle.

Finally, in addition to the general regulations related to VCS hardware and covered software described above, with respect to connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, BIS additionally proposes to

regulate VCS hardware and covered software by regulating the sale of completed connected vehicles that incorporate VCS hardware or covered software. In this circumstance, BIS understands from extensive engagement with connected vehicle manufacturers and automotive suppliers that persons who own, control, or direct the operations of the connected vehicle manufacturer would maintain an interest in the vehicle transactions that the connected vehicle manufacturer carries out. For example, this could include, but is not limited to, profit sharing agreements between a parent company and its U.S. subsidiary, or data sharing agreements between the same. BIS understands this to be standard for the automotive industry and would welcome comments on this issue. Additionally, because the PRC and Russian legal regimes discussed in Section IV of this notice could compel a PRC or Russia-based parent company of a connected vehicle manufacturer to provide those governments with information on or access to the operations of the U.S.-based connected vehicle manufacturer, BIS understands that the foreign parent company typically retains a legal right to access the data collected by the U.S. subsidiary, representing a foreign interest in that U.S. subsidiary and its connected vehicle sales.

BIS seeks comment on the nature of foreign interests in transactions related to the connected vehicle supply chain, including as described in the prohibitions outlined herein. BIS also seeks comment as to its understanding of the nature and presence of a Foreign Interest in property subject to the prohibitions described above, as well as whether there are other types of transactions that would involve Foreign Interests, as described above.

8. Hardware Bill of Materials

BIS proposes to define “Hardware Bill of Materials” or HBOM as a comprehensive list of parts, assemblies, documents, drawings, and components required to create a physical product. This term includes information identifying the manufacturer, related firmware, technical information, and descriptive information.

9. Import

BIS proposes to define “import” to mean, with respect to any article, the entry of such article into the United States Customs Territory. It does not include admission of an article from outside the United States into a foreign-trade zone for storage pending further assembly in the foreign-trade zone, or

shipment to a foreign country. This definition only applies to subpart D of 15 CFR part 791.

10. Item

BIS proposes to define “item” as a component or set of components with a specific function at the vehicle level. A system may also be considered an item if it implements a function. This definition is consistent with ISO/SAE Standard 21434.

11. Knowingly

BIS proposes to define “knowingly” to have the same meaning given to “knowledge” in the Export Administration Regulations (15 CFR 772.1). Knowledge of a circumstance (the term may be a variant, such as “know,” “reason to know,” or “reason to believe”) includes not only positive knowledge that the circumstance exists or is substantially certain to occur, but also an awareness of a high probability of its existence or future occurrence. Such awareness is inferred from evidence of the conscious disregard of facts known to a person and is also inferred from a person’s willful avoidance of facts.

12. Model Year

Consistent with the definition used by NHTSA, BIS proposes to define “model year” as the year used to designate a discrete vehicle model, irrespective of the calendar year in which the vehicle was actually produced, provided that the production period does not exceed 24 months. Throughout this proposed rule, BIS refers to both calendar year and model year when referring to the import of VCS Hardware, particularly for the submission of Declarations of Conformity (791.305) and the implementation timeline (791.308 (Exemptions)). BIS generally understands that most VCS hardware is imported into the United States already destined for a known, specific model year of vehicle. BIS also understands that some VCS hardware units may be imported without being associated with a specific vehicle model year. As such, the proposed rule provides separate timelines for each of these cases to accommodate business timelines for VCS hardware importers. BIS is particularly interested in comment on this approach.

13. Person Owned by, Controlled by, or Subject to the Jurisdiction or Direction of a Foreign Adversary

BIS proposes to define “person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary” to mean, (a) any person,

wherever located, who acts as an agent, representative, or employee, or any person who acts in any other capacity at the order, request, or under the direction or control, of a foreign adversary or of a person whose activities are directly or indirectly supervised, directed, controlled, financed, or subsidized in whole or in majority part by a foreign adversary; (b) any person, wherever located, who is a citizen or resident of a foreign adversary or a country controlled by a foreign adversary, and is not a United States citizen or permanent resident of the United States; (c) any corporation, partnership, association, or other organization with a principal place of business in, headquartered in, incorporated in, or otherwise organized under the laws of a foreign adversary or a country controlled by a foreign adversary; or (d) any corporation, partnership, association, or other organization, wherever organized or doing business, that is owned or controlled by a foreign adversary, to include circumstances in which any person identified in paragraphs (a) through (c) possesses the power, direct or indirect, whether or not exercised, through the ownership of a majority or a dominant minority of the total outstanding voting interest in an entity, board representation, proxy voting, a special share, contractual arrangements, formal or informal arrangements to act in concert, or other means, to determine, direct, or decide important matters affecting an entity.

14. Prohibited Transactions

BIS proposes to define “prohibited transactions” as, collectively, the transactions described in §§ 791.302 (Prohibited VCS hardware transactions), 791.303 (Prohibited covered software transactions), or 791.304 (Related prohibited transactions). The term prohibited transactions refers to the prohibitions on the knowing import of VCS hardware into the United States that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, as specified in section 791.302; the knowing Sale within, or import into, the United States of a completed connected vehicle containing covered software that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, as specified in § 791.303; and the knowing Sale of completed connected vehicles that incorporate VCS Hardware or covered software by connected vehicle

Manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, as specified in § 791.304.

15. Sale

BIS proposes to define “sale,” in the context of this subpart, as distributing for purchase, lease, or other commercial operations a new completed connected vehicle for a price, to include the transfer of completed connected vehicles from a connected vehicle manufacturer to a dealer or distributor, as those terms are defined in 49 U.S.C. 30102. This definition also applies to the related terms such as sell or selling. This would include direct-to-consumer sales of completed connected vehicles from the connected vehicle manufacturer to the ultimate purchaser.

16. Software Bill of Materials

BIS proposes to define “Software Bill of Materials” or SBOM as a formal and dynamic, machine-readable inventory detailing the software supply chain relationships between software components and subcomponents, including software dependencies, hierarchical relationships, and baseline software attributes, including author’s name, timestamp, supplier name, component name, version string, component hash, package URL, unique identifier, and dependency relationships to other software components.

BIS understands that this definition generally conforms to industry standards. However, BIS is specifically seeking comment on the feasibility, technical burden, cost, and effectiveness of identifying and disclosing to BIS the listed SBOM attributes.

17. Vehicle Connectivity System

BIS proposes to define “Vehicle Connectivity System” or VCS as a hardware or software item for a completed connected vehicle that has the function of enabling the transmission, receipt, conversion, or processing of radio frequency communications at a frequency over 450 megahertz. This definition would exempt most remote keyless entry fobs and immobilizers and certain internal wireless sensors and relays. VCS software is included in the definition of Covered Software.

18. VCS Hardware

BIS proposes to define “VCS hardware” as the following software-enabled or programmable components and subcomponents that support the function of Vehicle Connectivity Systems or that are part of an item that

supports the function of Vehicle Connectivity Systems: microcontroller, microcomputers or modules, systems on a chip, networking or telematics units, cellular modem/modules, Wi-Fi microcontrollers or modules, Bluetooth microcontrollers or modules, satellite navigation systems, satellite communication systems, other wireless communication microcontrollers or modules, and external antennas. VCS hardware does not include component parts that do not contribute to the communication function of VCS hardware (e.g., brackets, fasteners, plastics, and passive electronics). VCS hardware would include aftermarket devices not contained in a completed connected vehicle at sale but that could be later integrated into or attached to the vehicle to perform VCS functions.

BIS believes this definition appropriately identifies the various components, contained within a TCU or other connected systems of a connected vehicle, that facilitate off-board data transmission, and, thus, are most likely to pose the risks identified in Section IV of this notice. BIS specifically seeks comment on this list of components and the appropriateness of their inclusion to address the national security risks that BIS has identified in this notice.

19. VCS Hardware Importer

BIS proposes to define “VCS hardware importer” as a U.S. person importing VCS hardware for further manufacturing, integration, resale, or distribution. A connected vehicle manufacturer may be a VCS Hardware Importer if VCS hardware has already been installed in a connected vehicle when imported by the connected vehicle manufacturer.

This definition would capture OEMs, and tier 1 and tier 2 suppliers importing VCS hardware into the United States. BIS specifically seeks comment on the scope of this definition, particularly regarding whether it captures the breadth of market participants dealing in VCS Hardware.

20. United States

BIS proposes to define “United States” to mean the United States of America, the States of the United States, the District of Columbia, and any commonwealth, territory, dependency, or possession of the United States, or any subdivision thereof, and the territorial sea of the United States.

b. Prohibitions on Certain Transactions Related to Connected Vehicles

1. Prohibited Transactions

Under the proposed rule, VCS hardware importers would be

prohibited from knowingly importing into the United States any VCS hardware that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. BIS specifically seeks comment on this approach and whether additional components should be included in or excluded from this prohibition.

Connected vehicle manufacturers would be prohibited from knowingly Selling within the United States, or importing into the United States, completed connected vehicles that incorporate covered software designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

Connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia would also be prohibited from knowingly Selling in the United States completed connected vehicles that incorporate covered software or VCS hardware. As with other connected vehicle manufacturers, connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia participate in the design and development of VCS hardware and covered software, which are generally built to the manufacturers’ specifications. However, this prohibition applies even if connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia were not involved in the design or development of the VCS Hardware and Covered Software. Their Sale of those completed connected vehicles constitutes the supply of VCS hardware and covered software and is thus captured by this prohibition. To be clear, BIS anticipates that because of the role connected vehicle manufacturers play in the design and development of the key components in connected vehicles, in many cases, this prohibition will be duplicative of the other prohibitions in this proposed rule. BIS seeks comments on the efficacy of all of the proposed prohibitions detailed above.

As noted above, for the purposes of this proposed rule, BIS defines the term “person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary” to mean (a) any person, wherever located, who acts as an agent, representative, or employee, or any person who acts in any other capacity at the order, request, or under the direction or control, of a foreign

adversary or of a person whose activities are directly or indirectly supervised, directed, controlled, financed, or subsidized in whole or in majority part by a foreign adversary; (b) any person, wherever located, who is a citizen or resident of a foreign adversary or a country controlled by a foreign adversary, and is not a United States citizen or permanent resident of the United States; (c) any corporation, partnership, association, or other organization with a principal place of business in, headquartered in, incorporated in, or otherwise organized under the laws of a foreign adversary or a country controlled by a foreign adversary; or (d) any corporation, partnership, association, or other organization, wherever organized or doing business, that is owned or controlled by a foreign adversary, to include circumstances in which any person identified in paragraphs (a) through (c) possesses the power, direct or indirect, whether or not exercised, through the ownership of a majority or a dominant minority of the total outstanding voting interest in an entity, board representation, proxy voting, a special share, contractual arrangements, formal or informal arrangements to act in concert, or other means, to determine, direct, or decide important matters affecting an entity.

To provide further clarity regarding transactions involving VCS hardware and covered software that would be prohibited, BIS offers the following examples of persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC and Russia:

Example 1: Company A, incorporated in the United States, is a wholly owned subsidiary of Company B. Company B is a state-owned enterprise of the PRC or Russia. Because Company B is a state-owned enterprise, Company A would be considered “owned by” the PRC or Russia.

Example 2: Company A is a joint venture between Company B and Company C where Company C owns a majority share of Company A. Company B is a corporation incorporated in a third-party jurisdiction. Company C is a state-owned enterprise of the PRC or Russia. Company A would be considered “owned by” the PRC or Russia.

Example 3: Company A is majority owned in aggregate by multiple state-owned enterprises and state-owned investment funds of the PRC or Russia. Company A would be considered “owned by” the PRC or Russia.

Example 4: Company A, incorporated in the United States, is a subsidiary of

Company B. Company B is a private company incorporated in the PRC or Russia with its principal place of business in the PRC or Russia. Because Company B is subject to the jurisdiction of the PRC or Russia, Company B's subsidiary, Company A, is controlled by an entity subject to the jurisdiction of the PRC or Russia and would be considered "controlled by" and "subject to the direction of" the PRC or Russia.

Example 5: Company A is a multinational company where a majority of the voting power is held by Company B, a PRC or Russian government investment fund. Company A would be "controlled by" and "subject to the direction of" the PRC or Russia.

Example 6: Company A is a holding company organized in a tax-advantaged jurisdiction. Company A is publicly listed on a stock exchange and its corporate voting structure is characterized by Class A and Class B shares, Class B shares having ten times the voting power of Class A shares. If the aggregate voting power of shareholders subject to the jurisdiction of the PRC or Russia holding either Class A and Class B shares constitutes a majority or a dominant minority of total voting power, then Company A would be "controlled by" and "subject to the direction of" the PRC or Russia.

Example 7: Company A, a company that is organized under the laws of the PRC or Russia, owns a minority interest in Company B, a U.S. business. Based on special voting powers vested in that minority interest, Company A maintains certain veto rights that determine important matters affecting Company B, including the right to veto the dismissal of senior executives of Company B. Company B would be considered "controlled by" and "subject to the direction of" Company A, and therefore owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

Example 8: Company A is an entity incorporated in a third country and Company B is an entity incorporated in the PRC or Russia. Company A and Company B create a new joint venture, Company C, to design, develop, and manufacture a new product. Company A and Company B own minority shares of the joint venture while Company D, a holding company wholly owned by a PRC citizen, owns the largest minority share. If aggregate voting power of Company B and Company D constitutes majority or dominant minority voting share, Company C would be "controlled by" and "subject to the direction of" the PRC or Russia.

Example 9: Company A has eight members on its board of directors. Company A is characterized by a shareholder and corporate governance structure that requires a 75 percent supermajority for any significant business decision. Three of the members of the board are citizens of, and therefore subject to the jurisdiction of, the PRC or Russia. Because these three members make up 37.5 percent of the voting power of the board, they can block any supermajority and therefore determine, direct, or decide important matters affecting Company A. Company A would be "controlled by" or "subject to the direction of" the PRC or Russia.

Example 10: The PRC or Russian government, through an investment fund, acquires a 1% special management share in Company A. This share grants the PRC or Russian government the right to appoint a director to the board of Company A and veto certain key business decisions, such as major strategic changes or mergers. This share allows the government to influence Company A's operations and strategy. Company A would be "controlled by" the PRC or Russia.

Example 11: Company A maintains its principal place of business in the PRC or Russia. Company A would be "subject to the jurisdiction" of the PRC or Russia.

Example 12: Company A is a publicly listed U.S. corporate entity. Company A has a wholly owned subsidiary, Company B, that is organized under the laws of the PRC or Russia and manufactures goods in the PRC or Russia. Because Company B is organized under the laws of the PRC or Russia, Company B would be subject to the jurisdiction of the PRC or Russia. However, Company A is not subject to the jurisdiction of the PRC or Russia by nature of its subsidiary, Company B, being "subject to the jurisdiction" of the PRC or Russia.

Example 13: Company A is privately held and incorporated in the United States. One member of Company A's board of directors, Person X, a former chairman of the board of a large PRC corporation, has known ties to the government of the PRC, owns a large minority share of Company A, and has previously made significant investments in other companies founded by Company A's chief executive officer. Person X also facilitated a large minority investment in Company A by the large PRC corporation where they were previously chairman of the board. Person X's professional background indicates that they are directly or indirectly supervised, directed,

controlled, financed, or subsidized by the PRC government. The combination of Person X's close ties to Company A's CEO, Person X's ownership interest and ability to direct investment from large, highly regulated PRC corporate entities, and Person X's close ties to the PRC government indicate that Company A would be "subject to the direction" of the PRC.

BIS seeks comment on whether the definition of, and examples provided to illuminate, who is a "person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary," provides sufficient clarity regarding the circumstances under which the rule's prohibitions might apply.

For additional clarity in determining whether a transaction involving VCS hardware or covered software designed, developed, manufactured, or supplied by entities described above would be prohibited under the proposed rule, BIS offers the below examples. In offering these examples, BIS emphasizes that VCS hardware and covered software would not be considered designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, solely based on the country of citizenship of natural persons who are employed, contracted, or otherwise similarly engaged to participate in the design, development, manufacture, or supply of that VCS hardware or covered software:

Example 14: A U.S. person has a contractual relationship with a foreign person to import a cellular module, and the cellular module will later be integrated into a VCS for a completed connected vehicle. The U.S. person is, under the proposed rule, a VCS hardware importer. The U.S. person knows the cellular module was manufactured at a facility located in the PRC or Russia and is being imported through a third country. Since the entity manufacturing the module would, at a minimum, be "subject to the jurisdiction" of the PRC or Russia, the import of the module would be a prohibited transaction under the proposed rule, unless it qualifies for a general authorization or a specific authorization from BIS.

Example 15: A U.S. person imports a TCU that was assembled in a third country, but that contains a microcontroller that is manufactured in the PRC or Russia and is sold to the third-country assembler of the TCU. The U.S. person knows that the microcontroller was manufactured by an entity located in the PRC or Russia. As the microcontroller is included in the

definition of VCS hardware, the import of the TCU for a completed connected vehicle would be a prohibited transaction under the proposed rule unless it qualifies for a general authorization, or a specific authorization granted by BIS.

Example 16: A U.S. person imports a completed connected vehicle, making the U.S. person a connected vehicle manufacturer under the proposed rule's definition. The completed connected vehicle contains a TCU that operates software supporting off-vehicle connectivity above 450 MHz, and that software is designed, developed, or otherwise supplied (in whole or in part) by an entity located in the PRC or Russia. Under the proposed rule, the import of the completed connected vehicle would be prohibited, unless it was authorized by a general authorization or a Specific Authorization.

Example 17: A U.S. person who is a connected vehicle manufacturer that manufactures or assembles completed connected vehicles in the United States sells to a dealer within the United States a completed connected vehicle in which the vehicle's ADS software for object detection, classification, and decision making is proprietary software designed, developed, or supplied by an entity in the PRC or Russia. The sale or transfer of the completed connected vehicle would be a prohibited transaction under the proposed rule unless it qualifies for a general authorization or specific authorization granted by BIS.

Example 18: A U.S. person who is a connected vehicle manufacturer utilizes foreign VCS and ADS software development teams through various subsidiaries, joint ventures, and contract arrangements, some of which retain servicing obligations, contractual and licensing rights, and other interests in the software they have developed. One of those software development teams is located in the PRC or Russia, and as such, that software team is subject to the jurisdiction of the PRC or Russia. Given the role of PRC or Russian developers in the creation of the VCS or ADS software (covered software), the sale of a completed connected vehicle within the United States that integrates this proprietary covered software, would be a prohibited transaction under the proposed rule, unless it qualifies for a general authorization or specific authorization granted by BIS.

Example 19: A U.S. person who is a connected vehicle manufacturer utilizes VCS and ADS software development teams around the world through various subsidiaries, joint ventures, and contract

arrangements. One of those software development teams is comprised of individuals who are PRC or Russian citizens working in a foreign jurisdiction other than the PRC or Russia for a company that is not owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Although the individuals technically meet the definition of "person owned by, controlled by, or subject to the direction of a foreign adversary," the sole fact that PRC or Russian citizens work on the connected vehicle manufacturer's software development would not make the sale of a completed connected vehicle within the United States that integrates this VCS or ADS software a Prohibited Transaction under the proposed rule.

Example 20: Company A, which is a wholly owned subsidiary of a foreign corporation in which a PRC or Russian entity owns a controlling interest, imports completed connected vehicles that incorporate covered software and VCS hardware, none of which was originally designed, developed, manufactured, or supplied by an entity owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. In such rare circumstance where Company A did not participate in the design or development of the covered software or VCS hardware, Company A would submit (once per Model Year) a Declaration of Conformity for the import of the completed connected vehicles containing covered software and VCS hardware. However, any subsequent sale by Company A of such completed connected vehicle in the United States would be prohibited. For example, Company A subsequently sells such completed connected vehicles to a dealer in the United States. Because Company A is a person controlled by the PRC or Russia and has direct privileged access to the VCS hardware and covered software prior to the sale, the knowing sale by Company A of the completed connected vehicle with VCS hardware and covered software would be a prohibited transaction under the proposed rule, and a specific authorization from BIS would be required before engaging in such a transaction.

Example 21: Company A, a wholly owned subsidiary of a PRC or Russia corporation manufactures completed connected vehicles in the United States. The completed connected vehicles that Company A manufactures incorporate covered software and VCS hardware provided by Company B, a company that is not owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Because Company A

is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, participated in the design and development of the covered software or VCS hardware, and in any event, has direct and privileged access to its completed connected vehicles—including the incorporated covered software and VCS hardware—Company A's sale of the completed connected vehicles is a prohibited transaction under the proposed rule, and a specific authorization from BIS would be required before engaging in such a transaction.

c. Compliance

1. Declaration of Conformity

BIS proposes to require VCS Hardware Importers and connected vehicle manufacturers engaged in specified transactions to submit Declarations of Conformity to BIS certifying that they have not engaged in a prohibited transaction. Under the proposed rule, declarants would be responsible for submitting information to BIS, including documentation collected from suppliers of components of VCS hardware and from suppliers of covered software, to verify compliance with the regulations. These requirements include obtaining and analyzing the HBOMs for VCS hardware and the SBOMs for covered software and providing documentation of the steps the declarant took to verify that the transactions comply with the provisions of the rule. In an effort to facilitate compliance, BIS is not currently proposing to mandate particular due diligence requirements but would rather allow VCS hardware importers and connected vehicle manufacturers to provide evidence of their own efforts tailored to their unique operations. BIS seeks comment on this approach.

The proposed rule generally contemplates that Declarations of Conformity would be submitted in three instances by persons not engaged in prohibited transactions: (1) Declarations submitted by VCS hardware importers; (2) Declarations submitted by connected vehicle manufacturers importing completed connected vehicles containing covered software into the United States; and (3) Declarations submitted by connected vehicle manufacturers selling completed connected vehicles in the United States that they have manufactured or assembled in the United States and which contain covered software, so long as there is a continuing foreign interest in the covered software. Persons required to submit a Declaration of

Conformity need do so once per model year for units associated with a vehicle model year, or calendar year for units not associated with a vehicle model year, and only for the categories of transactions they seek to execute during that period. VCS hardware importers or connected vehicle manufacturers engaging in multiple transactions that require submissions of Declarations of Conformity under separate paragraphs of § 791.305 may, if they prefer, submit a single compiled Declaration of Conformity containing all required information for all transactions. For example, an OEM that manufactures or assembles completed connected vehicles in the United States, imports connected vehicles into the United States, and imports VCS hardware into the United States would be able to submit a single Declaration of Conformity based on vehicle make, model, and trim and VCS hardware that will be imported or manufactured that Model Year.

BIS believes that Declarations of Conformity will be an important tool for advancing the goals of this proposed rule, and addressing the emergency declared in E.O. 13873. Declarations of Conformity will first and foremost provide BIS with a means to verify VCS hardware importers' and completed connected vehicle manufacturers' compliance with the proposed prohibitions. Through extensive engagement with connected vehicle manufacturers and automotive suppliers, BIS has come to understand that connected vehicle supply chains are complex and often opaque, with potentially hundreds of suppliers for a single connected vehicle in a given model year. Such complexity and opacity could result in the incorporation into connected vehicles of VCS hardware and covered software that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of foreign adversaries, without the full knowledge of the connected vehicle manufacturer. While connected vehicle manufacturers typically have strong relationships with their immediate suppliers, to include the development of years-long supply contracts that span entire vehicle generations, their understanding of the deeper supply chain (to include who is supplying their suppliers) is substantially weaker. Additionally, while the COVID-19 pandemic and associated supply chain crisis forced connected vehicle manufacturers to more critically evaluate their hardware supply chains, illumination of software

supply chains remains largely unachieved. Consequently, BIS believes that the requirement to submit annual Declarations of Conformity will serve as an important mechanism for ensuring that parties subject to this proposed rule implement the due diligence and other procedures necessary to fully understand the supply chains for their VCS hardware and covered software and thus comply the proposed rule's prohibitions on the incorporation of VCS Hardware or covered software that has been designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

BIS also believes that the collection of annual Declarations of Conformity from connected vehicle manufacturers and VCS hardware importers would facilitate enforcement of the proposed rule, including by allowing BIS to proactively identify red flags and potential violations of the proposed prohibitions. For example, BIS may rely on the broad perspective provided by the Declarations of Conformity from multiple connected vehicle manufacturers and VCS hardware importers to identify previously undetected participation by PRC or Russian designers, developers, manufacturers, or suppliers that are subject to the prohibitions of this proposed rule yet remain entrenched in the U.S. connected vehicle supply chain. Additionally, these Declarations of Conformity would allow BIS to maintain an understanding of technological advancements and changes in the U.S. connected vehicle industry—both in hardware and software—and consequently enable BIS to propose updates to the rule as needed to maximize its effectiveness in mitigating the undue and unacceptable risks posed by the PRC and Russia while minimizing burden on industry.

The sections below explain in greater detail the types of Declaration of Conformity that would be required under the proposed rule. BIS seeks comment on this regulatory approach, including the necessity and efficacy of requiring Declarations of Conformity with respect to VCS hardware and covered software in which there is a Foreign Interest. BIS also seeks comment on the availability and efficacy of any alternative approach that would require a narrower set of VCS Hardware Importers and completed connected vehicle manufacturers to submit Declarations of Conformity, while still achieving the goals of the Declaration of Conformity requirement

and addressing the declared emergency under E.O. 13873.

i. Import of VCS Hardware

The Declaration of Conformity described in § 791.305(a)(1) would require VCS hardware Importers to provide information on the specific VCS hardware that the declarant plans to import into the United States for a given model year, or, for units not associated with a model year, a given calendar year. BIS proposes to require the Declaration of Conformity to contain the FCC ID number(s) of the VCS hardware, and, if applicable, any subcomponents in the VCS hardware that also have an FCC ID number. FCC regulations at 47 CFR 2.925 require any electronic device that emits RF waves, including those imported into the United States, to have an FCC ID number, which is used to identify and certify that the device meets the necessary regulatory standards for wireless communication. The proposed rule would additionally require VCS Hardware Importers to report all third-party information technology external endpoints to which the VCS Hardware is programmed to connect, including the country in which said endpoint is located and/or the identity and location of the service provider. This would include any third-party that is not the VCS hardware importer nor the final recipient, such as the connected vehicle manufacturer that integrates the VCS hardware and receives data on an episodic or ongoing basis from the VCS hardware. Additionally, VCS hardware importers would be required to submit an HBOM as part of the Declaration of Conformity. BIS would expect, consistent with the proposed definition for this term, this HBOM to include a comprehensive list of parts and technical information, including the provenance of subcomponents contained within the VCS hardware.

ii. Import of Completed Connected Vehicles

The Declaration of Conformity described in section 791.305(a)(2) would require connected vehicle manufacturers that import completed connected vehicles, including U.S.-based OEMs and foreign-headquartered OEMs with operations in the United States, to provide information to BIS on the make, model, and trim (if known) of the imported group of completed connected vehicles and the covered software contained within the completed connected vehicles. BIS proposes to require declarants to submit an SBOM for the covered software related to both VCS and ADS. The

minimum requirements for the SBOM are author's name, timestamp, supplier name, component name, version string, component hash, package URL, unique identifier, and dependency relationships to other software components. Declarants may submit additional SBOM information as evidence demonstrating the covered software is not sourced from PRC or Russian-linked entities. BIS seeks comment on all aspects of this SBOM requirement.

iii. Manufacture or Assembly of Completed Connected Vehicles for Sale in the United States

Similarly, this proposed rule, as described in section 791.305(a)(3), would require connected vehicle Manufacturers that manufacture or assemble completed connected vehicles for sale in the United States to submit a Declaration of Conformity that includes information on the make, model, and trim of the group of completed connected vehicles and the covered software contained within the completed connected vehicles that the connected vehicle manufacturer will sell for a Model Year. BIS emphasizes that this requirement would apply only to connected vehicle manufacturers whose vehicles incorporate covered software in which there is a foreign interest. Connected vehicle manufacturers who manufacture or assemble completed connected vehicles in the United States and whose vehicles contain no covered software in which there is a foreign interest would not be required to submit a Declaration of Conformity. However, given the global nature of automotive software supply chains, BIS anticipates that nearly all connected vehicle manufacturers of completed connected vehicles for Sale in the United States would be required to submit an annual Declaration of Conformity covering all completed connected vehicles by make, model, and trim to be manufactured for Sale in the United States for each Model Year. As detailed above, this requirement would include the submission of an SBOM for covered software incorporated into the group of completed connected vehicles.

iv. Procedures To Submit Declarations of Conformity

VCS Hardware Importers and connected vehicle manufacturers submitting a Declaration of Conformity under this rule would be required to submit the Declaration of Conformity to BIS annually, 60 days prior to the first sale or first import of a Vehicle Identification Number (VIN) series of completed connected vehicles

comprised of a single model year, or 60 days prior to the import of VCS hardware covered by the Declaration of Conformity. VCS hardware importers and connected vehicle manufacturers may, at their discretion, submit a combined Declaration of Conformity, or may submit separate Declarations of Conformity (e.g., one Declaration covering import of VCS hardware and another covering import of completed connected vehicles). Declarations of Conformity covering both the import or manufacture of completed connected vehicles and the import of VCS Hardware should be submitted by the earlier of the two reporting dates. connected vehicle manufacturers that would submit a Declaration of Conformity for the import of a group of completed connected vehicles into the United States should not submit a Declaration of Conformity related to the subsequent Sale of that same group of Completed Connected Vehicles. In the event of material changes that impact the content of the Declaration of Conformity, VCS hardware importers or connected vehicle manufacturers would be required to submit an updated Declaration of Conformity and an updated HBOM or SBOM within 30 days of such a change. Such changes may include changes in the suppliers of key subcomponents or functional aspects of the VCS hardware or covered software incorporated in the completed connected vehicle. BIS would make a web portal available on its website (<https://www.bis.gov>) through which VCS Hardware Importers and connected vehicle manufacturers may submit Declarations of Conformity.

2. General Authorizations

General Authorizations would allow certain VCS Hardware Importers and connected vehicle manufacturers to engage in otherwise prohibited transactions without the need to notify BIS prior to engaging in the transaction. connected vehicle manufacturers or VCS hardware importers (and entities under common control, including parents) who produce small quantities of completed connected vehicles or VCS hardware, which the proposed rule defines as fewer than 1,000 units in a calendar year, would be eligible for a general authorization. This is in line with requirements for high-volume and low-volume manufacturers found in 49 CFR part 565. BIS specifically seeks comment on this threshold for both completed connected vehicles and VCS Hardware. connected vehicle manufacturers would be eligible for a general authorization if the completed connected vehicle is otherwise subject

to a prohibition but will be used on public roadways fewer than 30 days in any calendar year. For purposes of this general authorization, each use of a completed connected vehicle on public roadways on a distinct calendar day will count toward the 30-day limit, regardless of the duration of a vehicle's use on a particular day. VCS hardware importers and connected vehicle manufacturers would also qualify for a general authorization for otherwise prohibited transactions involving completed connected vehicles incorporating covered software or VCS hardware if the completed connected vehicles are used only for testing display, or research purposes and not on public roads in the United States. Lastly, VCS hardware importers or connected vehicle manufacturers would qualify for a general authorization for the importation of completed connected vehicles incorporating covered software or the importation of VCS Hardware solely for the purposes of repair, alteration, or competition off public roads, and the vehicle or hardware will be reexported from the United States within one year of the time of import.

BIS proposes to allow persons using General Authorizations to self-certify their compliance with the applicable General Authorization. As such, these persons would not need to submit documentation to BIS but would be required to gather and maintain full records for a period of 10 years documenting compliance for all completed connected vehicles and VCS hardware covered by the general authorization. Furthermore, persons availing themselves of a general authorization would be required to continuously monitor for any changes that render a transaction ineligible for continued reliance on the general authorization. A VCS hardware importer or connected vehicle manufacturer that is no longer eligible for a general authorization would need to apply for and receive a specific authorization before engaging in an otherwise prohibited transaction. For example, connected vehicle manufacturers who import a certain model or trim of completed connected vehicles containing covered software that are originally used for display or testing purposes must seek a specific authorization before importing that model or trim of completed connected vehicle for more general use in the United States.

A connected vehicle manufacturer or VCS hardware importer that is a subsidiary, joint venture, affiliate, or other entity subject to the ownership, control, jurisdiction, or direction of the

PRC or Russia would be ineligible for general authorizations and would be required to apply for a specific authorization before engaging in an otherwise prohibited transaction.

3. Specific Authorizations

VCS hardware importers and connected vehicle manufacturers wishing to engage in an otherwise prohibited transaction who are ineligible for an exemption or general authorization would have to apply for and receive a specific authorization to engage in the otherwise prohibited transaction. The purpose of specific authorizations is to allow BIS on a case-by-case basis to determine the nature and scope of the undue or unacceptable risk to U.S. national security posed by transactions involving VCS hardware and covered software, including the extent of foreign adversary involvement in the transactions, as well as potential mitigations.

VCS hardware importers and connected vehicle manufacturers must not engage in an otherwise prohibited transaction until BIS grants the application for a specific authorization. If a party engages in a prohibited transaction prior to receiving a specific authorization from BIS, that transaction would constitute a violation of the regulation. Specific authorization requests will be reviewed on a case-by-case basis, and the time to reach a decision on an application for a specific authorization will vary based on the complexity of the case. However, BIS will respond to applicants with a processing update within 90 days of the initial application for a specific authorization, and typically endeavor to provide either a request for more information or a decision within that time period.

Applications for a specific authorization must contain complete information on the proposed transaction, including every party involved, an overview of the covered software and/or the VCS hardware designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, the intended use of the covered software and/or VCS hardware, and documentation to support the information contained in the application. Persons seeking a specific authorization would submit an application via a web portal that would be available on the BIS website. Applicants should take care to submit to BIS only one copy of an application pertaining to each transaction for which they seek specific authorization to avoid

processing delays. BIS may request additional information from an applicant about any matter related to the specific authorization request. In rare situations, as part of its review of an application for specific authorization, BIS may, in its sole discretion, request an oral briefing by the applicant and any other relevant parties. At any point between initial submission of an application for specific authorization and a final decision issued by BIS, an applicant may submit additional information to bolster the application or provide clarity on any aspect thereof.

When reviewing applications for a specific authorization, BIS will consider the factors that may pose undue or unacceptable risks, particularly as they relate to transactions that could result in the exfiltration of connected vehicle or U.S. persons' data, or the remote manipulation or operation of a connected vehicle. Examples of factors that BIS may consider include: the applicant's ability to limit PRC or Russian government access to, or influence over the design, development, manufacture, or supply of the VCS hardware or covered software; security standards used by the applicant and if such standards can be validated by BIS or a third-party; and other actions or proposals the applicant offers to implement as a way to mitigate undue or unacceptable risk.

BIS's decision regarding any application for specific authorization will apply only to the specific parties and transaction outlined in the application and described in the decision notice. Additionally, the decision notice from BIS to the applicant(s) may contain any conditions that must be met by the parties for a transaction to be authorized. Such conditions, which are subject to revision by BIS, may include technical controls (e.g., software validation) or operational controls (e.g., physical and logical access monitoring procedures), that are either permanent or temporary. These controls will focus on the supply chain element that involves a link to a foreign adversary to mitigate any undue or unacceptable risk posed by the transaction. For connected vehicle manufacturers owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, a specific authorization may include a requirement that all VCS hardware and covered software be assembled and integrated into the connected vehicle in the United States. In the approval letter for specific authorization, BIS will determine the effective date and duration of the authorization on a case-by-case basis.

While applicants denied authorizations would not be precluded from submitting new applications for specific authorizations with regard to different transactions (involving different parties and/or different covered software or VCS hardware), BIS will reconsider a previously denied application for a specific authorization only if the applicant demonstrates a material change in circumstances.

4. Exemptions

Transactions by VCS hardware importers and connected vehicle manufacturers would be exempt from the proposed prohibitions for a limited period. BIS proposes a shorter implementation period for transactions involving covered software and proposes a longer implementation period for transactions involving VCS hardware to allow market participants adequate time to establish alternative supply chains if necessary. This reflects BIS's understanding, and numerous public comments underscoring, that hardware supply chains for Connected Vehicles are complex and require multiple years to alter. VCS hardware importers would be permitted to engage in otherwise prohibited transactions involving VCS Hardware and would also be exempt from a requirement to submit a Declaration of Conformity for transactions not otherwise prohibited so long as: (1) for VCS hardware units not associated with a vehicle model year, the import of the VCS hardware takes place prior to January 1, 2029; or (2) the VCS hardware is integrated into a connected vehicle (completed or incomplete) or destined for a connected vehicle with a model year prior to 2030. Beginning January 1, 2029, any VCS hardware importer seeking to engage in a transaction subject to the VCS hardware prohibitions in § 791.302 (other than the import of a connected vehicle with a model year prior to 2030) would be required to obtain a specific authorization if the transaction is not otherwise permitted by a general authorization. Furthermore, VCS hardware importers seeking to import VCS hardware beginning on January 1, 2029, or VCS Hardware in completed connected vehicles or that is destined for connected vehicles starting with Model Year 2030, would be required to submit an annual Declaration of Conformity to BIS, unless obligated to seek a Specific Authorization. Connected vehicle manufacturers would be permitted to engage in otherwise Prohibited Transactions involving covered software designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to

the jurisdiction or direction of the PRC or Russia, so long as the completed connected vehicle that is imported or sold is of a model year prior to 2027. Beginning Model Year 2027 (as imported into or sold in the United States), any connected vehicle manufacturer seeking to engage in a prohibited transaction involving covered software specified in section 791.303 would be required to obtain a specific authorization if the transaction is not otherwise permitted by a general authorization. Furthermore, connected vehicle manufacturers would be required to submit an applicable Declaration of Conformity for imports or Sales of all completed connected vehicles beginning in Model Year 2027. Connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia would be permitted to engage in otherwise prohibited transactions so long as the completed connected vehicle that is Sold is of a Model Year prior to 2027. Beginning Model Year 2027 (as Sold in the United States), these particular connected vehicle manufacturers seeking to engage in a prohibited transaction specified in § 791.304 would be required to obtain a specific authorization if the transaction is not otherwise permitted by a general authorization.

5. Appeals

BIS proposes to create a mechanism by which any person whose application for a specific authorization is denied, whose specific authorization is suspended or revoked, or who has received a written notification of ineligibility for a general authorization may appeal that decision to the Under Secretary. Appeals must be submitted in writing by email or mail to the Office of the Under Secretary within 45 days of the date on the notice of the adverse administrative action by BIS. The appeal must detail how the party submitting the appeal has been directly and adversely affected by BIS's action, and the reasons that BIS's action should be reversed or otherwise modified. The Under Secretary, at his or her discretion, may delegate to the Deputy Under Secretary for Industry and Security or another BIS official the review of appeals, including arranging, at the official's discretion, informal hearings with relevant parties regarding the appeal.

Appellants may submit supplementary information in support of their appeal, whether *sua sponte* or at the request of the Under Secretary or the designated official, but, though the Under Secretary or designated official

generally would not consider additional information submitted *sua sponte* more than 30 days after submission of the original appeal. If the Under Secretary or designated official requests supplementary information, appellants will have no more than 30 calendar days to respond to the request. Appellants may also request an in-person informal hearing in writing at the time of submission. A hearing is not required, and the Under Secretary or designated official may, at his or her discretion, grant or deny a request for an informal hearing.

6. Advisory Opinions

In response to public comments regarding the ANPRM, BIS proposes to include a mechanism for BIS to issue advisory opinions, similar to the process outlined in the Export Administration Regulations (EAR). BIS anticipates this process will provide connected vehicle manufacturers, VCS hardware importers, and other interested parties with greater clarity about how to comply with the proposed rule on an as-needed basis. As with the EAR, BIS emphasizes that advisory opinions provided under this proposed rule would in no way serve as evidence that the ICTS transaction addressed in the opinion is not subject to the jurisdiction of another U.S. Government agency. BIS may publish on its website an advisory opinion that may be of broad interest to the public, with redactions where necessary to protect Confidential Business Information. To solicit an advisory opinion from BIS, persons would be required to submit a written request to BIS by email or through a portal that will be available on the BIS website. BIS will not accept advisory opinion requests submitted by mail. A request for an advisory opinion must contain contact information for the submitter as well as all current information on the prospective transaction to assist BIS in making a determination. This would include technical details on the involved VCS hardware or covered software, information on the completed connected vehicle (if applicable), the SBOM and/or HBOM for the covered software and/or VCS hardware, and any other supporting materials that the submitter assesses will assist BIS in determining if the transaction may be prohibited by this rule. Persons seeking an advisory opinion are encouraged to submit as much pertinent information as possible in the initial request for an advisory opinion, but BIS may request more information as needed to formulate its opinion. BIS will only consider advisory opinion requests for

actual, not hypothetical, prospective transactions in which all parties, as opposed to anonymous parties, are identified. Additionally, parties may only rely on an advisory opinion when engaging in a transaction if the original Advisory Opinion request contained complete and accurate information and only so long as such information remains accurate following the issuance of the Advisory Opinion.

7. "Is-Informed" Notices

BIS could notify connected vehicle manufacturers or VCS hardware importers, either through direct letters or through a **Federal Register** notice meant to inform a broader set of persons, that a transaction involving certain covered software, VCS hardware, or entities requires a specific authorization because it would constitute a Prohibited Transaction according to the terms of this proposed rule. Any person who engages in a transaction covered by an "Is-Informed" notice without first receiving a Specific Authorization from BIS would have knowledge that such transaction is prohibited and would therefore be in violation of the rule. Is-Informed notices may only be delivered by or at the direction of the Under Secretary or a BIS employee designated by the Under Secretary.

8. Recordkeeping and Reporting Requirements

BIS proposes to require connected vehicle manufacturers and VCS hardware importers to maintain complete records related to any transaction for which a Declaration of Conformity, general authorization, or specific authorization would be required by this rule, for a period of ten years. This recordkeeping requirement applies regardless of whether the transaction is subject to a general authorization, specific authorization, or whether the connected vehicle manufacturer or VCS hardware importer has not yet sought an authorization. BIS would expect said records to include all information pertinent to a general authorization or submitted when applying for a Specific Authorization, as well as business records related to the execution of the transaction, such as contracts, import records, bills of sale, relevant correspondence, and all other files specified in sections 791.312 and 791.313 to assess compliance with the rule.

All connected vehicle manufacturers and VCS hardware importers would be required to submit records when requested by BIS related to any transaction for which a Declaration of

Conformity, general authorization, or specific authorization would be required by this rule, whether or not said transaction was carried out under a general authorization, specific authorization, or without an authorization from BIS. As such, BIS would be allowed to request business records, before, during, or after the transaction in question has taken place.

d. Enforcement

1. Penalties

IEEPA authorizes this rulemaking. Thus, persons who violate, attempt to violate, conspire to violate, or knowingly cause a violation of this rule, if finalized, may be subject to civil and/or criminal penalties under IEEPA (50 U.S.C. 1705), depending on the circumstances of the violation. Potential violations of this proposed rule that would be subject to penalties include engaging in a prohibited transaction without an applicable general authorization or specific authorization, or failure to abide by the conditions enumerated in a specific authorization. Willfully providing false or fictitious information to the U.S. Government may be subject to criminal fines, imprisonment, or both. A civil penalty may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any authorization, order, regulation, or prohibition issued under IEEPA.

Under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, the specific maximum civil penalty will be adjusted by notice in the **Federal Register** effective each calendar year by the Office of the Secretary of the Department of Commerce. At the time of publishing of this proposed rule, the maximum civil penalty for violations of IEEPA is \$368,136 per violation and the maximum criminal penalty is \$1,000,000.

Under the proposed rule, should BIS have reason to believe that a violation has occurred and intends to issue a civil monetary penalty, it will inform the alleged violator through a written notice of the intent to impose a penalty ("Pre-Penalty Notice"). BIS will generally transmit the Pre-Penalty Notice electronically but may additionally issue a mailed notice. The recipient of a Pre-Penalty Notice may respond in writing to BIS to provide additional information or otherwise contest the penalty. BIS must receive this response within 30 days of the transmission of the original pre-penalty notice. A response to a pre-penalty notice does not constitute a formal appeal, but it allows the recipient of the pre-penalty

notice to contest facts set forth by BIS in the pre-penalty notice, provide exculpatory evidence, or otherwise respond to the pre-penalty notice. BIS may seek to initiate settlement discussions in the pre-penalty notice or may conduct separate outreach following transmission of the pre-penalty notice. Recipients of a pre-penalty notice may additionally request to initiate settlement discussions in their response to BIS or may conduct separate outreach to do so.

Following the delivery of the pre-penalty notice and after considering any responses from the alleged violator, BIS will inform the alleged violator in writing as to whether it has found that a violation in fact occurred. Should BIS find that a violation has indeed taken place and no settlement has been reached, BIS will issue a final penalty notice to the violator specifying the violation and determining the specific civil monetary penalty to be imposed. This penalty may not be appealed following the procedures in section 791.309, but is a final agency action that the violator may contest in the appropriate U.S. District Court.

Should a violator fail to pay the penalty as specified in the final penalty notice or fail to make alternative payment arrangements approved by BIS, BIS may refer the matter to the Department of Treasury for administrative collection or to the Department of Justice for collection via civil suit in U.S. District Court.

2. Finding a Violation

Under the proposed rule, there may be cases in which BIS determines that a violation has taken place but that a civil monetary penalty is not appropriate. In such cases, BIS would issue a finding of violation that identifies the violation. The finding of violation could also contain an administrative response other than a civil monetary penalty, such as an order to cease and desist from conduct or activities that are prohibited by the proposed rule. Consistent with the procedures listed above regarding a pre-penalty notice, recipients of a finding of violation may file a response within 30 days contesting the facts of the finding of violation and/or providing information relevant to BIS's determination of whether a violation has occurred. BIS will consider any new information and inform the party in writing whether a violation has or has not occurred. A recipient that does not respond within 30 days of receipt of the finding of violation will be deemed to have waived the right to respond. Any action taken in a finding of violation

issued by BIS constitutes a final agency action that is not subject to appeal following the procedures in section 791.309.

3. Severability

BIS intends for the provisions of this proposed rule, as finalized to be severable from each other. If a court holds that any provision in a final 15 CFR part 791, subpart D, is invalid or unenforceable, BIS intends that the remaining provisions of a final 15 CFR part 791, subpart D, as relevant, would continue in effect to the greatest extent possible. In addition, if a court holds that any such provision is invalid or unenforceable as to a particular person or circumstance, BIS intends that the provision would remain in effect as to any other person or circumstance. Depending on the circumstances and the scope of the court's order, BIS believes that the remaining provisions of a final rule likely could continue to function sensibly independent of any provision or application held invalid or unenforceable. For example, the prohibitions related to transactions involving VCS Hardware could continue to apply as intended, even if a court finds that the prohibitions on transactions involving ADS are invalid. Similarly, the proposed rule could be applied with respect to relevant hardware and software designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC, even if a court finds its application with respect to relevant hardware and software from Russian-linked persons is invalid.

e. Classification

1. Executive Order 12866

Executive Order 12866, as reaffirmed by Executive Order 13563 and amended by Executive Order 14094, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). This proposed rule has been designated a significant regulatory action by the Office of Information and Regulatory Affairs (OIRA) under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094.

2. Unfunded Mandates Reform Act of 1995

This proposed rule would not produce a federal mandate (under the regulatory provisions of title II of the

Unfunded Mandates Reform Act of 1995) for state, local, and tribal governments or the private sector.

3. Executive Order 13132 (Federalism)

This proposed rule does not contain policies having federalism implications requiring preparations of a Federalism Summary Impact Statement.

4. Executive Order 12630

(Governmental Actions and Interference With Constitutionally Protected Property Rights)

This proposed rule does not contain policies that have takings implications.

5. Executive Order 13175 (Consultation and Coordination With Indian Tribes)

The Department has analyzed this proposed rule under Executive Order 13175 and has determined that the action would not have a substantial direct effect on one or more Indian tribes, would not impose substantial direct compliance costs on Indian tribal governments, and would not preempt tribal law.

6. National Environmental Policy Act

The Department has reviewed this rulemaking action for the purposes of the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*). It has been determined that this proposed rule would not have a significant impact on the quality of the human environment.

7. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) (PRA) provides that an agency generally cannot conduct or sponsor a collection of information, and no person is required to respond nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA, unless that collection has obtained OMB approval and displays a currently valid Office of Management and Budget (OMB) Control Number.

This proposed rule will create new information collection requirements, which are subject to review and approval by OMB under the PRA. Specifically, this proposed rule would require connected vehicle manufacturers and VCS hardware importers to submit annual Declarations of Conformity certifying that their import of VCS hardware and/or import or manufacture of completed connected vehicles does not involve hardware or software subject to the prohibitions in this proposed rule. Additional requirements for the Declarations of Conformity include supplying technical information regarding the hardware or software in question and providing a

Bill of Materials for applicable software, hardware, or both.

Moreover, entities seeking specific authorizations from BIS to engage in otherwise prohibited transactions will have to file information with the Department, submissions of which are also subject to the PRA. Applications for a specific authorization would require, but are not limited to, a description of the nature of the otherwise prohibited transaction(s). For entities that are covered by a General Authorization, a self-certification, without need to notify BIS, would be required (*see* Section VI of the NPRM). BIS proposes to require connected vehicle manufacturers and VCS hardware importers to maintain complete records related to any transaction for which a Declaration of Conformity, general authorization, or specific authorization would be required by this rule for a period of ten years, consistent with IEEPA's statute of limitations. These records would include any transaction for which the connected vehicle manufacturer or VCS hardware importer has not yet sought an authorization. BIS expects said records to include all information submitted in applications, as well as business records related to the execution of any ICTS transaction subject to the rule, such as contracts, import records, bills of sale, and all other files BIS may deem pertinent in assessing compliance with this proposed rule. Lastly, entities seeking an advisory opinion from BIS would have to file information with the Department, though this is an optional process for parties looking for additional clarity on proposed transactions. BIS anticipates that this collection would be largely similar to its program in administering 15 CFR 748.3, as it would require similar information and the process for submission is analogous. BIS seeks comment on how many entities would request an advisory opinion in order to better understand the associated costs.

BIS estimates that the initial burden placed on applicable entities would be 180 to 240 hours. This estimate takes into account the one-time initial cost (in hours) per entity to comply with the rule, including reading and understanding the rule's provisions. Every subsequent year, BIS anticipates that the total annual cost burden (in hours) for applicable entities to implement the rule would be 100 to 500 hours.

BIS assesses that there are 42 to 281 entities potentially impacted by the proposed rule and that the initial cost burden for these entities is between \$30,964 and \$38,554. This estimate takes into account the one-time initial

cost per entity to comply with the rule, including reading and understanding the rule's provisions. Every subsequent year, BIS anticipates that the total annual cost burden for applicable entities to implement the rule will be \$16,133 to \$80,667 a year (average of operations manager, engineer, and lawyer hourly salaries in Table 2 [$\$484/\text{hour}/3 = \161.33] * [100 and 500 hours]). The annual cost burden placed on impacted entities includes (but is not limited to) producing the necessary HBOMs and SBOMs and documenting due diligence efforts. These hour and cost estimates are subject to variations among responsible entities due to application type. Declarations of Conformity will need to be submitted annually at minimum, while Specific Authorizations will need to be updated on an as-needed basis.

The estimated annual federal salary cost to the U.S. Government is \$1,130,000 [500 Declaration of Conformity/Specific Authorization notifications per year * two staff at a GS-13 salary ($\$113/\text{hour} * 2 = \$226/\text{hour}$) * average of 10 hours each to review each notification]. The \$113 per staff member per hour cost estimate for this information collection is consistent with the GS-scale salary data for a GS-13 Step 1 (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB.pdf>) multiplied by a factor of 2 to include the cost of benefits and overhead.

The total estimated annual cost to the U.S. Government is \$1,437,982.00. The calculation is as follows: Federal Employee Salaries (2 full-time employees) [$\$1,130,000.00$] + Federal Government Overhead @20% [$\$226,000.00$] + Legal Support (GS-15 Step 1 salary (multiplied by 2 to include the cost of benefits and overhead) @ 25%) [$\$81,982.00$] = \$1,437,982.00.

BIS requests comments on the information collection and recordkeeping requirements associated with this proposed rule. These comments will help BIS:

- i. Evaluate whether the information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;
- ii. Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;
- iii. Enhance the quality, utility, and clarity of the information to be collected; and
- iv. Minimize the burden of the information collection on those who are to respond (such as through the use of

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses).

8. Regulatory Flexibility Act

In compliance with Section 603 of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, the Department has prepared an initial regulatory flexibility analysis (IRFA) for this proposed rule. The IRFA describes the economic impacts the proposed action may have on small entities. The Department seeks comments on all aspects of the IRFA.

1. *A description of the reasons why action by the agency is being considered.* Connected Vehicles contain a growing number of connected components. While these components provide greater safety and convenience through features like Wi-Fi, Bluetooth, cellular telecommunication, and satellite connectivity, the incorporation of progressively complex hardware and software systems enabling vehicle connectivity has also increased the attack surfaces through which malign actors may exploit vulnerabilities to gain access to a vehicle. ICTS integral to Connected Vehicles present an undue or unacceptable risk to U.S. national security when those systems are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Furthermore, the PRC and Russia are able to leverage legal and regulatory regimes to compel private companies subject to their jurisdiction, including carmakers and vehicle suppliers, to cooperate with state security and intelligence services. Cooperation can include providing data, logical access, encryption keys, and other vital technical information, as well as by installing backdoors or bugs on equipment or in software updates, ultimately making vehicle equipment exploitable by foreign adversaries. Such privileged access potentially enables the PRC and Russia to exfiltrate sensitive data collected by Connected Vehicles through their components and allow remote manipulation for vehicles driven by U.S. persons.

2. *A succinct statement of the objectives of, and legal basis for, the proposed rule.* The Department is proposing this rule pursuant to authority under the International Emergency Economic Powers Act (IEEPA) (50 U.S.C. 1701, *et seq.*), the National Emergencies Act (NEA) (50 U.S.C. 1601, *et seq.*), and Section 301 of Title 3, United States Code, and in accordance with E.O. 13873, “Securing

the Information and Communications Technology and Services Supply Chain,” 84 FR 22689 (May 17, 2019), which delegated to the Secretary of Commerce (Secretary) certain authorities provided to the President by IEEPA, the NEA, and Section 301 of Title 3 of the United States Code. In accordance with the National Emergencies Act, the President has declared each year since E.O. 13873 was published that the national emergency declared in E.O. 13873 regarding the ICTS supply chain continues to remain in effect.

To address identified risks to national security from ICTS transactions, E.O. 13873 directs the Secretary (in consultation with other agency heads identified in E.O. 13873) to review any ICTS transaction, defined as any acquisition, importation, transfer, installation, dealing in, or use of any ICTS by any person, or with respect to any property, subject to United States jurisdiction, where the transaction involves any property in which a foreign country or national has any interest. When the Secretary, in consultation with the appropriate agency heads, finds that an ICTS transaction or class of ICTS transactions pose undue risks (including of sabotage, subversion, or catastrophic effects on the security and resiliency of U.S. critical infrastructure), or unacceptable risks to national security or the security and safety of U.S. persons, the Secretary may identify the ICTS transaction as prohibited by Section 1 of E.O. 13873 or impose mitigation measures on the ICTS transaction or class of ICTS transactions reviewed. E.O. 13873 additionally provides that the Secretary issue rules establishing criteria by which particular technologies or market participants may be categorically included in or categorically excluded from prohibitions established pursuant to the E.O.

3. *A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.* BIS anticipates that the entities primarily responsible for compliance with this regulation will be connected vehicle manufacturers and VCS hardware importers. BIS assesses, based on publicly available information, that the U.S. connected vehicle market is dominated by a small set of manufacturers, few of which would be considered “small entities” under the Small Business Administration’s definitions. The Small Business Administration small business size standard for NAICS 336110: Automobile and Light Duty Motor Vehicle Manufacturing and NAICS 336120:

Heavy Duty Truck Manufacturing is 1,500 employees or fewer. However, BIS has limited data on how many of these suppliers engage in covered software and VCS hardware transactions, and therefore cannot estimate how many of these suppliers qualify as small entities. BIS specifically seeks comments on the number of suppliers engaged in covered software and VCS Hardware transactions in the United States, as well as the percentage of those entities that might or could qualify as small entities.

4. *A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.* As stated above, connected vehicle manufacturers and VCS hardware importers will bear the majority of the proposed rule’s compliance costs. BIS estimates that the recordkeeping and compliance burden placed on responsible small entities would involve operations managers, engineers, and lawyers. On an annual basis, these entities will need to, at minimum and if applicable, submit a Declaration of Conformity certifying that their import of VCS hardware and/or import or manufacture of completed connected vehicles does not involve hardware or software subject to the prohibitions in this proposed rule. The Declaration of Conformity would also include technical information regarding the hardware or software in question and a Bill of Materials for applicable software, hardware, or both.

BIS proposes to require connected vehicle manufacturers and VCS hardware importers to maintain complete records related to any transaction for which a Declaration of Conformity, general authorization, or specific authorization would be required by this rule, for a period of ten years, consistent with IEEPA’s statute of limitations. These records would be expected to assist BIS’s enforcement efforts for the prohibitions in the proposed rule. The required records would include those related to any transaction that is subject to a general authorization (including records of any entities producing fewer than 1,000 connected vehicle or VCS hardware units in a calendar year), any transaction that is subject to a specific authorization, and any transaction involving covered software or VCS Hardware for which the connected vehicle manufacturer or VCS hardware importer has not yet sought an

authorization. BIS expects such records to include all information submitted in applications, as well as business records related to the execution of any ICTS transaction subject to the rule, such as contracts, import records, bills of sale, and all other files BIS may deem pertinent in assessing compliance with this proposed rule.

Because small entities could avail themselves of a general authorization, the maintenance of records in support of such authorization would be the only compliance requirement. These records would serve as the small entities' self-certification, which does not need to be submitted to BIS. A general authorization would allow the VCS hardware importer and/or connected vehicle manufacturer to engage in the otherwise prohibited transaction, without the need to notify or seek approval from BIS. General Authorizations would be available only in a narrow set of circumstances in which the conditions of the otherwise prohibited transaction appropriately mitigate the level of risk associated with the particular transaction. Such conditions would include, for example, when VCS hardware is imported from the PRC or Russia solely for testing purposes, or where the completed connected vehicle that incorporates VCS hardware or covered software from the PRC or Russia will not be driven on public roads for more than 30 calendar days per year. Those availing themselves of a general authorization would be required to continuously monitor their use of the VCS hardware or completed connected vehicles covered by the general authorization to ensure the authorization still applies. If a change would render the transaction ineligible for a general authorization, such as a change in the vehicle's use, the VCS hardware importer or connected vehicle manufacturer would be required to apply for a specific authorization and to cease engaging in such transaction unless and until a specific authorization is granted. For example, if a completed connected vehicle that incorporates covered software or VCS Hardware that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia is no longer engaged in display, research, or testing, the VCS hardware importer or the connected vehicle manufacturer would be required to seek a specific authorization. Similarly, if the VCS Hardware Importer or connected vehicle manufacturer exceeds total model year production of 1,000 units, or

if a completed connected vehicle that incorporates covered software or VCS hardware that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia is to be used on public roadways for 30 or more days in any calendar year, the VCS hardware importer or connected vehicle manufacturer would be required to seek a specific authorization from BIS.

5. *An identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule.* This rulemaking does not duplicate or conflict with any Federal rules.

6. *A description of any significant alternatives to the proposed rule that accomplish the stated objectives of Executive Order 13984 and Executive Order 14110 and applicable statutes and that would minimize any significant economic impact of the proposed rule on small entities.* The Department has proposed what it believes to be "the least restrictive means necessary [by] tailor[ing] the prohibition to address the undue or unacceptable risk" (see 15 CFR part 791.109(c)) and believes that the proposed rule will materially address significant risks for the United States or U.S. persons while balancing the overall compliance costs of the rule and minimizing the impact on small entities. Below is a description of alternatives considered by the Department; the Department invites comment on these alternatives.

No-action alternative: While the alternative of taking no action would be less costly for connected vehicle manufacturers and VCS hardware importers, the no-action alternative is not preferred because the risks presented by foreign adversary involvement in the ICTS of the U.S. connected vehicle market could lead to catastrophic negative events for U.S. national security, including the security of U.S. critical infrastructure, and U.S. persons.

More stringent alternatives: The Department considered several more stringent regulatory approaches, including regulating additional connected vehicle component systems not included in this proposed rule. For example, the Department considered the risks posed by various connected vehicle component systems, including ADS, telematics, battery management systems (BMS), automated driver assistance systems (ADAS), vehicle operating systems (OS), and satellite or cellular telecommunication systems. The Department currently believes the

best approach to address the risks posed by connected vehicles and connected vehicle components from foreign adversary nations is to focus the scope of the NPRM on PRC- and Russian-supplied VCS hardware (which encompasses both telematics and satellite or cellular telecommunication systems) and covered software. Other systems under consideration, such as ADAS, seem to have a low risk of data exfiltration or, in the case of vehicle OS, would involve regulation that is expected to be extremely burdensome on industry.

Preferred alternative: The proposed rule is the preferred alternative. BIS assesses that the regulatory approach outlined in this proposed rule would have the highest net benefit for connected vehicle manufacturers, VCS hardware importers, and consumers. BIS currently believes the provisions in the proposed rule are also to be, for the reasons articulated above and in the NPRM's preamble, "the least restrictive means necessary. . .to address the undue or unacceptable risk" presented by covered software and VCS hardware in connected vehicles.

List of Subjects in 15 CFR Part 791

Business and industry, Communications, Computer technology, Critical infrastructure, Executive orders, Foreign persons, Investigations, National security, Penalties, Technology, Telecommunications.

Elizabeth L.D. Cannon,

Executive Director, Office of Information and Communications Technology and Services, Bureau of Industry and Security, United States Department of Commerce.

For the reasons set out in the preamble, 15 CFR part 791, is proposed to be amended as follows:

PART 791—SECURING THE INFORMATION AND COMMUNICATIONS TECHNOLOGY AND SERVICES SUPPLY CHAIN

■ 1. The authority citation for part 791 continues to read as follows:

Authority: 50 U.S.C. 1701et seq.; 50 U.S.C. 1601et seq.; E.O. 13873, 84 FR 22689; E.O. 14034, 86 FR 31423.

■ 2. Amend part 791 by adding subpart D, consisting of § 791.300 through § 791.319, to read as follows:

Subpart D—ICTS Supply Chain: Connected Vehicles

Sec.

791.300 Purpose and scope.

791.301 Definitions.

791.302 Prohibited VCS hardware transactions.

- 791.303 Prohibited covered software transactions.
- 791.304 Related prohibited transactions.
- 791.305 Declaration of Conformity.
- 791.306 General authorizations.
- 791.307 Specific authorizations.
- 791.308 Exemptions.
- 791.309 Appeals.
- 791.310 Advisory opinions.
- 791.311 "Is-Informed" notices.
- 791.312 Recordkeeping.
- 791.313 Reports to be furnished on demand.
- 791.314 Penalties.
- 791.315 Pre-penalty notice; settlement.
- 791.316 Penalty imposition.
- 791.317 Administrative collection; referral to United States Department of Justice.
- 791.318 Finding of violation.
- 791.319 Severability.

Subpart D—ICTS Supply Chain: Connected Vehicles

§ 791.300 Purpose and scope.

The inclusion in Connected Vehicles of certain ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of certain foreign adversaries poses undue or unacceptable risks to U.S. national security. To address these undue or unacceptable risks, it is the purpose of this subpart to:

(a) Prohibit ICTS transactions that involve certain software and hardware that, are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the People's Republic of China (PRC) or the Russian Federation (Russia), as defined in § 791.4 and that enable connected vehicle Automated Driving Systems or Vehicle Connectivity Systems, as defined in this subpart;

(b) Implement compliance mechanisms such as Declarations of Conformity to ensure that no Prohibited Transactions, as defined in this subpart, have occurred;

(c) Provide general authorizations and a mechanism for specific authorizations for certain transactions that are otherwise prohibited by this subpart, but where any undue or unacceptable risks to national security can be reasonably mitigated, based on defined criteria and conditions; and

(d) Incentivize connected vehicle manufacturers, VCS hardware importers, and related suppliers to adopt measures to help secure the U.S. ICTS supply chain for connected vehicles.

§ 791.301 Definitions.

The following definitions apply only to this subpart, 15 CFR part 791 subpart

D. For additional definitions applicable to all of part 791, *see* 15 CFR 791.2. If a term is defined differently in this subpart than in 15 CFR 791.2, the definition listed in this section will apply to this subpart.

Automated Driving System means hardware and software that, collectively, are capable of performing the entire dynamic driving task for a completed connected vehicle on a sustained basis, regardless of whether it is limited to a specific operational design domain (ODD).

Completed connected vehicle means a connected vehicle that requires no further manufacturing operations to perform its intended function. For the purposes of this subpart, the integration of an Automated Driving System into a connected vehicle constitutes a manufacturing operation for a completed connected vehicle.

Connected vehicle means a vehicle driven or drawn by mechanical power and manufactured primarily for use on public streets, roads, and highways, that integrates onboard networked hardware with automotive software systems to communicate via dedicated short-range communication, cellular telecommunications connectivity, satellite communication, or other wireless spectrum connectivity with any other network or device. Vehicles operated only on a rail line are not included in this definition.

Connected vehicle manufacturer means a U.S. person

(1) Manufacturing or assembling completed connected vehicles in the United States; and/or

(2) Importing completed connected vehicles for sale in the United States.

Covered software means the software-based components, in which there is a foreign interest, executed by the primary processing unit of the respective systems that are part of an item that supports the function of Vehicle Connectivity Systems or Automated Driving Systems at the vehicle level. Covered software does not include firmware, which is characterized as software specifically programmed for a hardware device with a primary purpose of controlling, configuring, and communicating with that hardware device. Covered software also does not include open-source software that can be freely used, modified, and distributed by anyone, with both access to the source code and the ability to contribute to the software's development and improvement unless that open-source software has been modified for proprietary purposes and not redistributed or shared.

FCC ID Number means the unique alphanumeric code identifying a product subject to certification by the Federal Communications Commission composed of a:

- (1) Grantee code; and
- (2) Product code.

Foreign interest, for purposes of this subpart, means any interest in property of any nature whatsoever, whether direct or indirect, by a non-U.S. person.

Hardware Bill of Materials (HBOM) means a comprehensive list of parts, assemblies, documents, drawings, and components required to create a physical product, including information identifying the manufacturer, related firmware, technical information, and descriptive information.

Import means, in the context of this subpart, with respect to any article, the entry of such article into the United States Customs Territory. It does not include admission of an article from outside the United States into a foreign-trade zone for storage pending further assembly in the foreign-trade zone or shipment to a foreign country.

Item means a component or set of components with a specific function at the vehicle level. A system may also be considered an item if it implements a function.

Knowingly means having knowledge of a circumstance (the term may be a variant, such as "know," "reason to know," or "reason to believe"), to include not only positive knowledge that the circumstance exists or is substantially certain to occur, but also an awareness of a high probability of its existence or future occurrence. Such awareness is inferred from evidence of the conscious disregard of facts known to a person and is also inferred from a person's willful avoidance of facts.

Model year means the year used to designate a discrete vehicle model, irrespective of the calendar year in which the vehicle was actually produced, provided that the production period does not exceed 24 months.

Prohibited transactions mean, collectively, the transactions described in 791.302 (Prohibited VCS Hardware Transactions), 791.303 (Prohibited Covered Software Transactions), or 791.304 (Related Prohibited Transactions) of this subpart.

Person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary means:

(1) Any person, wherever located, who acts as an agent, representative, or employee, or any person who acts in any other capacity at the order, request, or under the direction or control, of a foreign adversary or of a person whose activities are directly or indirectly

supervised, directed, controlled, financed, or subsidized in whole or in material part by a foreign adversary;

(2) Any person, wherever located, who is a citizen or resident of a foreign adversary or a country controlled by a foreign adversary, and is not a United States citizen or permanent resident of the United States;

(3) Any corporation, partnership, association, or other organization with a principal place of business in, headquartered in, incorporated in, or otherwise organized under the laws of a foreign adversary or a country controlled by a foreign adversary; or

(4) Any corporation, partnership, association, or other organization, wherever organized or doing business, that is owned or controlled by a foreign adversary, to include circumstances in which any person identified in paragraphs (a) through (c) possesses the power, direct or indirect, whether or not exercised, through the ownership of a majority or a dominant minority of the total outstanding voting interest in an entity, board representation, proxy voting, a special share, contractual arrangements, formal or informal arrangements to act in concert, or other means, to determine, direct, or decide important matters affecting an entity.

Sale means, in the context of this subpart, distributing for purchase, lease, or other commercial operations a new completed connected vehicle for a price, to include the transfer of completed connected vehicles from a connected vehicle manufacturer to a dealer or distributor, as those terms are defined in 49 U.S.C. 30102. This definition also applies to the related terms such as *Sell* or *Selling*.

Software Bill of Materials (SBOM) means a formal and dynamic, machine-readable inventory detailing the software supply chain relationships between software components and subcomponents, including software dependencies, hierarchical relationships, and baseline software attributes, including author's name, timestamp, supplier name, component name, version string, component hash package URL, unique identifier, and dependency relationships to other software components.

Vehicle Connectivity System (VCS) means a hardware or software item for a completed connected vehicle that has the function of enabling the transmission, receipt, conversion, or processing of radio frequency communications at a frequency over 450 megahertz.

VCS hardware means the following software-enabled or programmable components and subcomponents that

support the function of Vehicle Connectivity Systems or are part of an item that supports the function of Vehicle Connectivity Systems: microcontroller, microcomputers or modules, systems on a chip, networking or telematics units, cellular modem/modules, Wi-Fi microcontrollers or modules, Bluetooth microcontrollers or modules, satellite navigation systems, satellite communication systems, other wireless communication microcontrollers or modules, and external antennas. VCS hardware does not include component parts that do not contribute to the communication function of VCS hardware (e.g., brackets, fasteners, plastics, and passive electronics).

VCS hardware importer means a U.S. person importing VCS hardware for further manufacturing, integration, resale, or distribution. A connected vehicle manufacturer may be a VCS hardware importer if VCS hardware has already been installed in a connected vehicle when imported by the connected vehicle manufacturer.

United States means the United States of America, the States of the United States, the District of Columbia, and any commonwealth, territory, dependency, or possession of the United States, or any subdivision thereof, and the territorial sea of the United States.

§ 791.302 Prohibited VCS hardware transactions.

(a) VCS hardware importers are prohibited from knowingly importing VCS hardware that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

(b) In the context of this subpart, VCS hardware will not be considered to be designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, solely based on the country of citizenship of natural persons who are employed, contracted, or otherwise similarly engaged to participate in the design, development, manufacture, or supply of the VCS hardware.

§ 791.303 Prohibited covered software transactions.

(a) Connected vehicle manufacturers are prohibited from knowingly importing into the United States completed connected vehicles that incorporate covered software, designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

(b) Connected vehicle manufacturers are prohibited from knowingly selling in the United States completed connected vehicles that incorporate covered software, designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

(c) In the context of this subpart, covered software will not be considered to be designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, solely based on the country of citizenship of natural persons who are employed, contracted, or otherwise similarly engaged to participate in the design, development, manufacture, or supply of the Covered Software.

§ 791.304 Related prohibited transactions.

Connected vehicle manufacturers who are persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, are prohibited from knowingly selling in the United States completed connected vehicles that incorporate VCS hardware or covered software.

§ 791.305 Declaration of Conformity.

(a) *Requirements*—(1) *Import of VCS hardware*: A VCS hardware importer may not import VCS Hardware as part of a transaction that is not otherwise prohibited by this subpart without first submitting to the Bureau of Industry and Security (BIS) a Declaration of Conformity, unless otherwise specified by this subpart. The Declaration of Conformity shall include:

(i) The name and address of VCS hardware importer;

(ii) A certification that the declarant has not knowingly engaged in a prohibited VCS hardware transaction;

(iii) The FCC ID Number associated with the VCS hardware and, if applicable, of the subcomponents contained therein;

(iv) A list of third-party external endpoints to which the VCS hardware connects, including the country where each endpoint is located and/or the identity and location of the service provider;

(v) If known, the make, model, and trim of the completed connected vehicles for which the VCS hardware is intended;

(vi) A HBOM for the VCS hardware that is the subject of the Declaration of Conformity;

(vii) Documentation of the VCS hardware importer's due diligence efforts, to include independent or hired third-party research, to ensure the VCS

hardware listed in the HBOM is not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia;

(viii) If applicable, an indication of whether the submission is an update to a prior Declaration of Conformity and the date of the last submission;

(ix) Identifying information for an individual point of contact (including name, email address, and phone number); and,

(x) Any additional material information the VCS hardware importer would like to submit.

(2) *Import of completed connected vehicles:* A connected vehicle manufacturer may not import completed connected vehicles containing covered software as part of a transaction that is not otherwise prohibited by this subpart without first submitting to BIS a Declaration of Conformity, unless otherwise specified by this subpart. The Declaration of Conformity shall include:

(i) The name and address of the connected vehicle manufacturer;

(ii) A certification that the declarant has not knowingly engaged in a prohibited covered software transaction;

(iii) The make, model, trim, and Vehicle Identification Number (VIN) series applicable to the completed connected vehicles;

(iv) A SBOM for the covered software that is the subject of the Declaration of Conformity. At a minimum, the SBOM must include author's name, timestamp, supplier name, component name, version string, component hash, package URL, unique identifier, and dependency relationships to other software components.

(v) Documentation of the connected vehicle manufacturer's due diligence efforts, to include independent or hired third-party research, to ensure that the covered software listed in the SBOM is not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia;

(vi) If applicable, an indication of whether the submission is an update to a prior Declaration of Conformity and the date of the last submission;

(vii) Identifying information for an individual point of contact (including name, email address, and phone number); and

(viii) Any additional material information the connected vehicle manufacturer would like to submit.

(3) *Sale of completed connected vehicles manufactured in the United States:* Connected vehicle

manufacturers that manufacture or assemble completed connected vehicles in the United States that incorporate covered software as part of a transaction that is not otherwise prohibited by this subpart, may not Sell completed connected vehicles in the United States without first submitting to BIS a Declaration of Conformity, unless otherwise specified by this subpart. If there is no Foreign Interest in the covered software that is incorporated in completed connected vehicles manufactured or assembled in the United States, the connected vehicle manufacturer need not submit a Declaration of Conformity. If submitting a Declaration of Conformity, it shall include:

(i) The name and address of the connected vehicle manufacturer;

(ii) A certification that there is a foreign interest in the covered software that is incorporated in the completed connected vehicles that will be Sold in the United States;

(iii) A certification that the declarant has not knowingly engaged in a prohibited covered software Transaction;

(iv) The make, model, trim, and VIN series applicable to the completed connected vehicles;

(v) A SBOM for the covered software that is the subject of the Declaration of Conformity. At a minimum, the SBOM must include author's name, timestamp, supplier name, component name, version string, component hash, package URL, unique identifier, and dependency relationships to other software components.

(vi) Documentation of the connected vehicle manufacturer's due diligence efforts, to include independent or hired third-party research, to ensure the covered software listed in the SBOM is not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia;

(vii) If applicable, an indication of whether the submission is an update to a prior Declaration of Conformity and the date of the last submission;

(viii) Identifying information for an individual point of contact (including name, email address, and phone number); and

(ix) Any additional material information the connected vehicle manufacturer would like to submit.

(b) *Procedures to submit Declarations of Conformity.* Connected vehicle manufacturers and VCS Hardware Importers shall submit Declarations of Conformity annually as specified in this section and any time there is a material

change that makes a prior Declaration of Conformity or associated HBOM or SBOM no longer accurate.

(1) Connected Vehicles Manufacturers seeking to import or manufacture for Sale in the United States a completed connected vehicle containing covered software shall submit a Declaration of Conformity 60 days prior to the first import or first sale of each model year of completed connected vehicles, grouped by make, model, and trim.

(2) VCS hardware importers seeking to import any VCS hardware shall submit a Declaration of Conformity 60 days prior to the first import of VCS hardware for each model year for units associated with a vehicle model year, or calendar year for units not associated with a vehicle model year. VCS hardware importers may submit a single Declaration of Conformity detailing all VCS Hardware models that will be imported in the Model Year or calendar year.

(3) Entities that are both connected vehicle manufacturers and VCS hardware importers may, but are not required to, submit a single compiled Declaration of Conformity detailing all required information specified in 791.305 of this subpart. Any compiled Declaration of Conformity shall be submitted 60 days prior to the first import or first sale of the model year of completed connected vehicles or 60 days prior to the first import of VCS hardware, whichever occurs first.

(4) Declarants must notify BIS of any material change in the contents of a previously submitted Declaration of Conformity by submitting a revised Declaration of Conformity within 30 days following any such changes.

(c) Declarations of Conformity must be delivered to BIS using an official electronic reporting option as specified by BIS on its website (<https://www.bis.gov>).

(d) *Connected vehicle introduced by means of a fraudulent or false declaration.* Any person who engages in a prohibited VCS hardware transaction or a prohibited covered software transaction and submits a false or fraudulent Declaration of Conformity made without reasonable cause to believe the truth of the declaration, may incur penalties as defined in § 791.314.

§ 791.306 General authorizations.

(a) VCS hardware importers and connected vehicle manufacturers may qualify for a general authorization if they meet the stated requirements or conditions to engage in otherwise prohibited transactions. Persons availing themselves of any general authorization are required to maintain

records documenting each otherwise prohibited transaction for a period of 10 years as specified in § 791.312.

(b) *General course of procedure.* VCS hardware importers and connected vehicle manufacturers may self-certify, without need to notify BIS, that they meet the requirements for one or more of the following general authorizations:

(1) The connected vehicle manufacturer or VCS hardware importer and entities under common control, including parents, engaging in an otherwise prohibited transaction produces a total model year production of completed connected vehicles containing covered software or total model year production of VCS hardware is less than 1,000 units;

(2) The completed connected vehicle that incorporates covered software or VCS hardware will be used on public roadways on fewer than 30 calendar days in any calendar year;

(3) The completed connected vehicle that incorporates covered software or the VCS hardware will be used solely for the purpose of display, testing, or research, and will not be used on public roadways; or

(4) The completed connected vehicle that incorporates covered software or the VCS hardware is imported solely for purposes of repair, alteration, or competition off public roads and will be reexported within one year from the time of import;

(c) *Change in use.* In the event of any change in the use of a completed connected vehicle or VCS hardware associated with a general authorization, a VCS hardware importer or connected vehicle manufacturer availing itself of a general authorization must determine if it still qualifies for the general authorization or if it must apply for a specific authorization.

(d) *Inspection.* VCS hardware importers and connected vehicle manufacturers availing themselves of a general authorization are subject to audit and inspection by BIS.

(e) *Restrictions.* VCS Hardware importers and connected vehicle manufacturers shall not avail themselves of any general authorization if any one or more of the following apply:

(1) BIS has notified the VCS hardware importer or connected vehicle manufacturer that it is not eligible for a general authorization.

(2) The VCS Hardware Importer or connected vehicle manufacturer is a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

§ 791.307 Specific authorizations.

(a) BIS may provide Specific Authorizations permitting a VCS hardware importer or connected vehicle manufacturer to engage in otherwise prohibited transactions. Persons receiving a specific authorization are required to maintain records for a period of 10 years as required in § 791.312 and submit reports and statements in accordance with the instructions specified in each specific authorization.

(b) *General course of procedure.* Prohibited transactions subject to this subpart, and that are not otherwise permitted under an exemption or a general authorization, may be permitted under a specific authorization. It is the policy of BIS not to grant applications for specific authorizations for transactions that are permitted by a general authorization.

(c) *Applications for specific authorizations.* Applications for specific authorizations shall include, at a minimum, a description of the nature of the otherwise prohibited transaction(s), including the following:

(1) The identity of the parties engaged in the transaction, including relevant corporate identifiers and information sufficient to identify the ultimate beneficial ownership of the transacting parties;

(2) An overview of the VCS hardware or covered software that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia;

(3) If known, the make, model, and trim of the completed connected vehicle in which the VCS hardware or covered software will be integrated;

(4) The intended function of the VCS hardware or covered software;

(5) Documentation to support the information contained in the application, including ISO/SAE 21434 Threat Analysis and Risk Assessments, to include an assessment on the applicant's ability to limit PRC or Russian government access to, or influence over the design, development, manufacture or supply of the VCS hardware or covered software; security standards used by the applicant with respect to the VCS hardware or covered software; other actions and proposals such as technical controls (*i.e.*, software validation) or operational controls (*i.e.*, physical and logical access monitoring procedures), the applicant intends to take to mitigate undue or unacceptable risk; and

(6) Any other information that BIS may request after receipt of the initial application for a Specific Authorization.

(d) *Application submission procedures.* A VCS hardware importer or connected vehicle manufacturer who seeks to engage in an otherwise prohibited transaction must submit an application for specific authorization in writing prior to engaging in the transaction and await a decision from BIS prior to engaging in the transaction. This application must be delivered to BIS using an official electronic reporting option as specified by BIS on its website (<https://www.bis.gov>).

(e) *Additional conditions.* Only one application for a specific authorization should be submitted to BIS for each otherwise prohibited transaction; multiple parties submitting an application for a specific authorization for the same transaction may result in processing delays.

(f) *Information to be supplied.* An applicant may be required to furnish additional information as BIS deems necessary to assist in making a decision. The applicant may present additional information concerning an application for a specific authorization at any time before BIS makes its decision with respect to the application.

(g) *Review and decisions.*

Applications for specific authorization will be reviewed on a case-by-case basis and determine conditions to be applied to each specific authorization as may be needed to mitigate any risk that arises as a result of the otherwise prohibited transaction. Such review may include an evaluation of the risks and potential mitigation measures proposed by the applicant for the particular transaction, including, but not limited to, risks of data exfiltration from, and remote manipulation or operation of, the connected vehicle; the extent and nature of foreign adversary involvement in the design, development, manufacture, or supply of the VCS hardware or covered software; the applicant's ability to limit PRC or Russian government access to, or influence over the design, development, manufacture or supply of the VCS hardware or covered software; security standards used by the applicant and if such standards can be validated by BIS or a third-party; other actions and proposals the applicant intends to take to mitigate undue or unacceptable risk. BIS will advise each applicant of the decision respecting the filed application.

(h) *Processing period.* BIS shall respond to any application for a specific authorization with a status update and a request for additional information or documents, if any, within 90 days after receipt of the application.

(i) *Scope.* (1) Unless otherwise specified in the authorization, a specific

authorization permits the transaction only:

- (i) Between the parties identified in the specific authorization;
- (ii) With respect to the otherwise prohibited transaction(s) described in the authorization; and
- (iii) If the conditions specified in the specific authorization are satisfied. The applicant must inform any other parties identified in the specific authorization of the authorization's scope and specific conditions.

(2) Any specific authorization obtained based on a false or misleading representation in the application or in any document submitted in connection with the application under this section shall be deemed void as of the date of issuance, and the applicant may incur penalties as specified in § 791.314.

(3) As a condition for the issuance of any specific authorization, the applicant may be required to file reports with respect to the otherwise prohibited transactions authorized by the specific authorization in such form and at such times and places as may be prescribed in the specific authorization or otherwise communicated to the applicant by BIS. Reports should be sent in accordance with the instructions provided in the applicable specific authorization.

(j) *Effect of denial.* BIS's denial of a specific authorization may be appealed as described in § 791.309 and does not preclude parties from filing an application for a specific authorization for a separate otherwise prohibited transaction. The applicant may at any time request, by written correspondence, reconsideration of the denial of an application based on new material facts or changed circumstances.

(k) *Effect of specific authorization.* (1) No specific authorization issued under this subpart, or otherwise issued by BIS, permits or validates any prohibited transaction effected prior to the issuance of such specific authorization unless specifically provided for in the specific authorization.

(2) No regulation, ruling, instruction, or authorization permits any prohibited transaction under this subpart unless the regulation, ruling, instruction or Authorization is issued by BIS and specifically refers to this subpart. No regulation, ruling, instruction, or authorization referring to this subpart shall be deemed to permit any prohibited transaction prohibited by any provision of this subpart unless the regulation, ruling, instruction, or authorization specifically refers to such provision. Any specific authorization permitting any otherwise prohibited transaction has the effect of removing

those prohibitions from the transaction, but only to the extent specifically stated by the terms of the specific authorization. Unless the specific authorization otherwise specifies, such an authorization does not create any right, duty, obligation, claim, or interest in, or with respect to, any property that would not otherwise exist under ordinary principles of law.

(3) Nothing contained in this subpart shall be construed to supersede the requirements established under any other provision of law or to relieve a person from any requirement to obtain an authorization from another department or agency of the U.S. Government in compliance with applicable laws and regulations subject to the jurisdiction of that department or agency.

(l) *Amendment, modification, or rescission.* Except as otherwise provided by law, any Specific Authorization or instructions issued thereunder may be amended, modified, or rescinded by BIS at any time.

§ 791.308 Exemptions.

(a) VCS hardware importers may engage in prohibited transactions described in § 791.302 without an authorization as required under §§ 791.306 and 791.307, and are exempt from submitting Declarations of Conformity with respect to all other transactions, as described in § 791.305 provided that:

(1) For VCS Hardware units not associated with a vehicle model year, the import of the VCS hardware occurs prior to January 1, 2029; or

(2) The VCS hardware is associated with a vehicle model year prior to 2030 or the VCS hardware is imported as part of a connected vehicle with a model year prior to 2030.

(b) Connected vehicle manufacturers may engage in prohibited transactions described in § 791.303 without authorization as required under §§ 791.306 or 791.307 and are exempt from submitting Declarations of Conformity with respect to all other transactions, as described in § 791.305, provided that the completed connected vehicle that incorporates covered software described in § 791.303(a)(1) was manufactured prior to Model Year 2027.

(c) Connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia may engage in prohibited transactions described in section 791.304 without Authorization as required under §§ 791.306 or 791.307, and are exempt from submitting Declarations of Conformity to all other

transactions, provided that the completed connected vehicle that incorporates VCS hardware and/or covered software was manufactured prior to Model Year 2027.

§ 791.309 Appeals.

(a) *Scope.* Any person directly and adversely affected by any of the listed administrative actions taken by BIS pursuant to this subpart may appeal to the Under Secretary for reconsideration of that administrative action. Only the following types of administrative actions are subject to the appeals procedures described in this subpart:

(1) Denial of an application for specific authorization;

(2) Suspension or revocation of an issued specific authorization; or

(3) Determination of ineligibility for a general authorization.

(b) *Designated appeals reviewer and coordinator.* The Under Secretary may delegate to the Deputy Under Secretary of Commerce for Industry and Security or to another BIS official the authority to review and decide the appeal, and to exercise any other function of the Under Secretary under this section. In addition, the Under Secretary may designate any employee of BIS to be an appeals coordinator to assist in the review and processing of an appeal under this subpart.

(c) *Appeals procedures.* An appeal under this subpart must be submitted to the Under Secretary by email or at the following address: Bureau of Industry and Security, U.S. Department of Commerce, Room 3898, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230 not later than 45 days after the date appearing on the written notice of administrative action. The appeal must include a full written statement in support of the appellant's position. The appeal must include a precise statement of the reasons that the appellant believes that the administrative action has a direct and adverse effect and should be reversed or modified. The Under Secretary or the designated official may request additional information that would be helpful in resolving the appeal and may accept additional submissions. The Under Secretary or the designated official will not ordinarily accept any submission filed sua sponte more than 30 days after the filing of the appeal.

(d) *Request for informal hearing.* In addition to the written statement submitted in support of an appeal, an appellant may request, in writing, at the time an appeal is filed, an opportunity for an informal hearing. A hearing is not required, and the Under Secretary or the designated official may grant or deny a

request for an informal hearing at the Under Secretary or the designated official's sole discretion. Any hearings will be held in the District of Columbia unless the Under Secretary or the designated official determines, based upon good cause shown, that another location would be preferable.

(e) *Informal hearing procedures.* If a hearing request is granted, the Under Secretary or the designated official may provide an opportunity for the appellant to make an oral presentation at an informal hearing based on the materials previously submitted by the appellant or made available by the Department. The Under Secretary or the designated official may require that any facts in controversy be covered by an affidavit or testimony given under oath or affirmation. The rules of evidence prevailing in courts of law do not apply, and all evidentiary material deemed by the Under Secretary or the designated official to be relevant and material to the proceeding, and not unduly repetitious, will be received and considered. The Under Secretary or the designated official has the authority to limit the number of people attending the hearing, to impose any time or other limitations deemed reasonable, and to determine all procedural questions. A transcript of an informal hearing shall not be made, unless the Under Secretary or the designated official determines that the national interest or other good cause warrants it, or the appellant requests a transcript. If the appellant requests, and the Under Secretary or the designated official approves the taking of, a transcript, the appellant will be responsible for paying all expenses related to production of the transcript. Any person designated by the Under Secretary to conduct an informal hearing shall submit a written report containing a summary of the hearing and recommended action to the Under Secretary.

(f) *Decisions.* In addition to the documents specifically submitted in connection with the appeal, the Under Secretary or the designated official may consider any recommendations, reports, or other relevant documents available to BIS in determining the appeal, but shall not be bound by any such information, nor prevented from considering any other relevant information, or consulting with any other person or groups, in making a decision. The Under Secretary or the designated official may adopt any other procedures deemed necessary and reasonable for considering an appeal, including by providing the appellant with an interim or proposed decision and offering the appellant an opportunity to provide

comments. The Under Secretary or the designated official shall decide an appeal within a reasonable time after receipt of the appeal. The decision shall be issued to the appellant in writing and contain a statement of the reasons for the action and address any arguments contrary to the decision presented by the appellant. The decision of the Under Secretary or the designated official shall be final.

(g) *Effect of appeal.* Acceptance and consideration of an appeal shall not affect any administrative action, pending or in effect, unless the Under Secretary or the designated official, upon request by the appellant and with opportunity for a response, grants a stay.

§ 791.310 Advisory opinions.

(a) VCS hardware importers and connected vehicle manufacturers may request an advisory opinion from BIS as to whether a prospective transaction is subject to a prohibition in this subpart. The entire transaction that is the subject of the advisory opinion request must be an actual, as opposed to hypothetical, transaction and involve disclosed, as opposed to anonymous, parties to the transaction.

(b) Advisory opinion requests must be made in writing, and may be delivered to BIS by email, through the BIS website, or by any other means that BIS may prescribe.

(c) Persons submitting advisory opinion requests are encouraged to provide as much information as possible to assist BIS in making a determination, to include the following information:

(1) The name, title, and telephone and email address of the person to contact;

(2) The submitter's complete address comprised of street address, city, state, country, and postal code;

(3) All available information identifying the parties to the prospective transaction;

(4) Complete information regarding the VCS hardware and/or covered software and any descriptive literature, brochures, technical specifications, or papers that provide sufficient technical detail to enable BIS to verify whether the prospective transaction would constitute a prohibited transaction as defined in this subpart;

(5) For connected vehicle manufacturers: the make, model, and trim level, or other identifying information number of the completed connected vehicle;

(6) For VCS hardware Importers: the identification of the system; and, if known, the make, model, and trim of the group of completed connected vehicles for which the equipment is intended;

(7) An SBOM and/or an HBOM; and
(8) Any other information that the submitter believes to be material to the prospective transaction.

(d) Each person that submits an advisory opinion request shall provide any additional information or documents that BIS may thereafter request in its review of the matter.

(e) Each advisory opinion can be relied upon by the requesting party or parties to the extent the disclosures made pursuant to this subpart were accurate and complete and to the extent the disclosures continue accurately and completely to reflect circumstances after the date of the issuance of the advisory opinion. An advisory opinion will not restrict enforcement actions by any agency other than BIS. It will not affect a requesting party's obligations to any other agency or under any statutory or regulatory provision other than those specifically discussed in the Advisory Opinion.

(f) BIS may publish on its website an advisory opinion that may be of broad interest to the public, with redactions where necessary to protect confidential business information.

§ 791.311 "Is-Informed" notices.

(a) BIS may inform VCS hardware importers or connected vehicle manufacturers either individually by specific notice or, for larger groups, through a separate notice published in the **Federal Register**, that a specific authorization is required because an activity could constitute a prohibited transaction.

(b) Specific notice that a specific authorization is required may be given only by, or at the direction of, the Under Secretary or a BIS official designated by the Under Secretary.

§ 791.312 Recordkeeping.

Except as otherwise provided, VCS hardware importers and connected vehicle manufacturers shall keep a full and accurate record of each transaction engaged in for which a Declaration of Conformity, general authorization, or specific authorization would be required under sections 791.305, 791.306, or 791.307, regardless of whether these transactions are effected pursuant to a general authorization, specific authorization, or otherwise, and such record shall be available for examination for at least 10 years after the date of such transactions.

§ 791.313 Reports to be furnished on demand.

(a) VCS hardware importers and connected vehicle manufacturers are required to furnish under oath, in the

form of reports or as otherwise specified by BIS, from time to time and at any time as may be required by BIS, complete information relative to any transaction involving the import of VCS hardware or the import or Sale of completed connected vehicles incorporating covered software, regardless of whether such transaction is effected pursuant to an authorization or otherwise, subject to the provisions of this subpart. BIS may require that such reports include the production of any books, contracts, letters, papers, or other hard copy or electronic documents relating to any transactions, in the custody or control of the persons required to make such reports. BIS may, through any person or agency, conduct investigations, hold hearings, administer oaths, examine witnesses, receive evidence, take depositions, and require by subpoena the attendance and testimony of witnesses and the production of any books, contracts, letters, papers, and other hard copy or electronic documents relating to any matter under investigation, regardless of whether any report has been required or filed in connection therewith.

(b) For purposes of paragraph (a) of this section, the term "document" includes any written, recorded, or graphic matter or other means of preserving thought or expression (including in electronic format), and all tangible things stored in any medium from which information can be processed, transcribed, or obtained directly or indirectly, including correspondence, memoranda, notes, messages, contemporaneous communications such as text and instant messages, letters, emails, spreadsheets, metadata, contracts, bulletins, diaries, chronological data, minutes, books, reports, examinations, charts, ledgers, books of account, invoices, air waybills, bills of lading, worksheets, receipts, printouts, papers, schedules, affidavits, presentations, transcripts, surveys, graphic representations of any kind, drawings, photographs, graphs, video or sound recordings, and motion pictures or other film.

(c) Persons providing documents to BIS pursuant to this section must submit documents electronically. Acceptable formats include Portable Document Format (PDF) and Microsoft Excel. Files with embedded, encrypted, or password protected content will not be accepted.

§ 791.314 Penalties.

(a) Section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705) (IEEPA) is applicable to

violations of the provisions of any general authorization, Specific authorization, regulation, order, directive, instruction, or prohibition issued by or pursuant to the direction or authorization of the Secretary of Commerce (Secretary) pursuant to this subpart or otherwise under IEEPA.

(1) A civil penalty not to exceed the amount set forth in section 206 of IEEPA may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any exemption, general authorization, specific authorization, regulation, order, directive, instruction, or prohibition issued under this subpart.

(2) A person who willfully commits, willfully attempts to commit, willfully conspires to commit, or aids or abets in the commission of a violation of any exemption, general authorization, specific authorization, regulation, order, directive, instruction, or prohibition issued under this subpart is subject to criminal penalties and may, upon conviction, be fined not more than \$1,000,000, or if a natural person, be imprisoned for not more than 20 years, or both.

(b) The civil penalties provided in IEEPA are subject to adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, as amended, 28 U.S.C. 2461 note).

(c) The criminal penalties provided in IEEPA are subject to adjustment pursuant to 18 U.S.C. 3571.

(d) Pursuant to 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the U.S. Government, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, imprisoned, or both.

(e) Violations of this subpart may also be subject to other applicable laws.

§ 791.315 Pre-penalty notice; settlement.

(a) *When required.* If BIS has reason to believe that there has occurred a violation of any provision of this subpart or a violation of the provisions of any exemption, general authorization, specific authorization, regulation, order, directive, instruction, or prohibition issued by or pursuant to the direction or authorization of the Secretary pursuant to this subpart or otherwise under

IEEPA and determines that a civil monetary penalty is warranted, BIS will issue a pre-penalty notice informing the alleged violator of BIS's intent to impose a monetary penalty. A Pre-Penalty Notice shall be in writing and issued electronically to the alleged violator. The pre-penalty notice may be issued whether or not another agency has taken any action with respect to the matter.

(b) *Response—(1) Right to respond.* An alleged violator may respond to a Pre-Penalty Notice in writing to BIS.

(2) *Deadline for response.* A response to a Pre-Penalty Notice must be made within 30 days as set forth below. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond.

(i) *Computation of time for response.* A response to a Pre-Penalty Notice must be electronically transmitted on or before the 30th day after the date of delivery by BIS.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of BIS, only upon specific request to BIS.

(3) *Form and method of response.* A response to a pre-penalty notice need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof, contain information sufficient to indicate that it is in response to the pre-penalty notice, and include the BIS identification number listed on the pre-penalty notice. A digital signature is acceptable.

(4) *Information that should be included in response.* Any response should set forth in detail why the alleged violator either believes that a violation of the provisions of this subpart did not occur and/or why a civil monetary penalty is otherwise unwarranted under the circumstances. The response should include all documentary or other evidence available to the alleged violator that supports the arguments set forth in the response. BIS will consider all relevant materials submitted in the response.

(c) *Settlement.* Settlement discussions may be initiated by BIS, the alleged violator, or the alleged violator's authorized representative.

(d) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with BIS prior to a written submission regarding the specific allegations contained in the pre-penalty notice must be preceded by a written letter of representation, unless the pre-penalty notice was served upon

the alleged violator in care of the representative.

§ 791.316 Penalty imposition.

(a) If, after considering any written response to the pre-penalty notice and any relevant facts, BIS determines that there was a violation by the alleged violator named in the pre-penalty notice and that a civil monetary penalty is appropriate, BIS may issue a penalty notice to the violator containing a determination of the violation and the imposition of the monetary penalty.

(b) The issuance of the penalty notice shall constitute final agency action. The violator may seek judicial review of that final agency action in federal district court.

§ 791.317 Administrative collection; referral to United States Department of Justice.

In the event that the violator does not pay the penalty imposed pursuant to this subpart or make payment arrangements acceptable to BIS, the matter may be referred for administrative collection measures by the Department of the Treasury or to the United States Department of Justice for appropriate action to recover the penalty in a civil suit in a federal district court.

§ 791.318 Finding of Violation.

(a) *When issued.* (1) BIS may issue an initial finding of violation that identifies a violation if BIS:

(i) Determines that there has occurred a violation of any provision of this subpart, or a violation of the provisions of any exemption, general authorization, specific authorization, regulation, order, directive, instruction, or prohibition issued by or pursuant to the direction or authorization of the Secretary pursuant to this subpart or otherwise under IEEPA;

(ii) Considers it important to document the occurrence of a violation; and

(iii) Concludes that an administrative response is warranted but that a civil monetary penalty is not the most appropriate response.

(2) An initial finding of violation shall be in writing and may be issued whether or not another agency has taken any action with respect to the matter.

(b) *Response—(1) Right to respond.* An alleged violator may contest an initial Finding of Violation by providing a written response to BIS.

(2) *Deadline for response; default determination.* A response to an initial Finding of Violation must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond, and the initial Finding of Violation will become final and will constitute final agency action. The violator may seek judicial review of that final agency action in federal district court.

(i) *Computation of time for response.* A response to an initial finding of violation must be electronically transmitted on or before the 30th day after the date of delivery by BIS.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of BIS, only upon specific request to BIS.

(3) *Form and method of response.* A response to an initial finding of violation need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof, contain information sufficient to indicate that it is in response to the initial finding of violation, and include the BIS identification number listed on the initial finding of violation. A digital signature is acceptable.

(4) *Information that should be included in response.* Any response

should set forth in detail why the alleged violator either believes that a violation of the provisions of this subpart did not occur and/or why a finding of violation is otherwise unwarranted under the circumstances. The response should include all documentary or other evidence available to the alleged violator that supports the arguments set forth in the response. BIS will consider all relevant materials submitted in the response.

(c) *Determination—(1) Determination that a finding of violation is warranted.* If, after considering the response, BIS determines that a final finding of violation should be issued, BIS will issue a final finding of violation that will inform the violator of its decision. Any action taken in a final finding of violation shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

(2) *Determination that a finding of violation is not warranted.* If, after considering the response, BIS determines a finding of violation is not warranted, then BIS will inform the alleged violator of its decision not to issue a final finding of violation.

§ 791.319 Severability.

If any provision of this subpart is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action or judicial review, the provision is to be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding will be one of utter invalidity or unenforceability, in which event the provision will be severable from this part and will not affect the remainder thereof.

[FR Doc. 2024–21903 Filed 9–23–24; 8:45 am]

BILLING CODE 3510–33–P

Reader Aids

Federal Register

Vol. 89, No. 187

Thursday, September 26, 2024

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids **202-741-6000**

Laws **741-6000**

Presidential Documents

Executive orders and proclamations **741-6000**

The United States Government Manual **741-6000**

Other Services

Electronic and on-line services (voice) **741-6020**

Privacy Act Compilation **741-6050**

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, SEPTEMBER

71153-71794.....	3
71795-72278.....	4
72279-72714.....	5
72715-72956.....	6
72957-73248.....	9
73249-73554.....	10
73555-74104.....	11
74105-74828.....	12
74829-75444.....	13
75445-75944.....	16
75945-76388.....	17
76389-76708.....	18
76709-77010.....	19
77011-77444.....	20
77445-77752.....	23
77753-78198.....	24
78199-78782.....	25
78783-79124.....	26

CFR PARTS AFFECTED DURING SEPTEMBER

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.

2 CFR	2024.....76397
1800.....	75947
5900.....	75445
3 CFR	No. 2024-12 of September 15, 2024.....77761
Proclamations:	
10795.....	72279
10796.....	72283
10797.....	72285
10798.....	72287
10799.....	72289
10800.....	72291
10801.....	72293
10802.....	72295
10803.....	73249
10804.....	73555
10805.....	73557
10806.....	74105
10807.....	74829
10808.....	75945
10809.....	76389
10810.....	76391
10811.....	76393
10812.....	76709
10813.....	76711
10814.....	77765
10815.....	77767
10816.....	78199
Executive Orders:	
14126.....	73559
Administrative Orders:	
Memorandums:	
Memorandum of August 9, 2024.....	71795
Memorandum of August 16, 2024.....	71799
Memorandum of August 23, 2024.....	71801
Memorandum of September 6, 2024.....	77753
Memorandum of September 13, 2024.....	77755
Memorandum of September 13, 2024.....	77757
Notices:	
Notice of September 6, 2024.....	73251
Notice of September 9, 2024.....	74101
Notice of September 9, 2024.....	74103
Notice of September 18, 2024.....	77011
Presidential Determinations:	
No. 2024-10 of August 9, 2024.....	71797
No. 2024-11 of September 13,	
5 CFR	
1200.....	72957
1201.....	72957
1203.....	72957
1209.....	72957
2641.....	74107
6 CFR	
Proposed Rules:	
37.....	74137
7 CFR	
1205.....	75445
4284.....	75762
Proposed Rules:	
915.....	77037
944.....	77037
989.....	74851
3555.....	76745
8 CFR	
217.....	78783
9 CFR	
317.....	73253
381.....	73253
412.....	73253
10 CFR	
50.....	77769
72.....	72299, 72304
73.....	73257
1703.....	73258
Proposed Rules:	
50.....	76750
72.....	72342, 72344
1008.....	73312, 77040
11 CFR	
110.....	78785
113.....	78201
Proposed Rules:	
104.....	72346
112.....	78826
12 CFR	
5.....	78207
201.....	78221
204.....	78222
1002.....	76713
Proposed Rules:	
613.....	72759
13 CFR	
121.....	74109
Proposed Rules:	
126.....	72763, 76751

14 CFR

39	72309, 72312, 72966, 72968, 72971, 72974, 72976, 73260, 73262, 73264, 73267, 73269, 75460, 75462, 75464, 75470, 75472, 75949, 76399, 76401, 76403, 76406, 76408, 76411, 76413, 77013, 77445, 77769, 77772, 78223, 78226, 78229, 78231, 78826, 78827
61	73271
71	72981, 73272, 73273, 74131, 76713, 77015
97	75475
401	76714
413	76714
415	76714
431	76714
435	76714
437	76714
440	76714
450	76714
460	76714

Proposed Rules:

25	73604
39	73003, 73009, 73014, 73316, 73608, 75507, 75977, 76752, 77045, 77049, 77457, 78260, 78262, 78785, 78791
71	71189, 71191, 71863, 72765, 73020, 73022, 75510, 77053, 77055, 78831, 78832, 78834

15 CFR

734	71803
736	72926
738	72926
740	71803, 72926
742	72926
743	72926
744	71803, 75476
746	71803
764	75477
766	75477
772	72926
774	71803, 72926

Proposed Rules:

702	73612
730	78835
732	78835
734	78835
736	78835, 78836
740	78835
744	78835, 78836
774	78836
791	79088
908	77057

16 CFR

Proposed Rules:

1112	73024
1226	73320
1250	73024

17 CFR

1	71803, 78793
3	71803, 78793
4	78793
5	71803
9	71803
10	71803
11	71803
12	71803
13	71803

14	71803
15	71803
16	71803
17	71803
18	71803
20	71803
23	71803
30	71803, 78793
31	71803
37	71803
41	71803
43	71803, 78793
45	71803
46	71803
49	71803
75	78793
140	71803
142	71803
144	71803
145	71803
146	71803
147	71803
148	71803
149	71803
150	71803
155	71803
160	71803
162	71803
165	71803
170	71803
171	71803
270	73764
274	73764

18 CFR

801	78233
Proposed Rules:	
35	74161

19 CFR

12	73274, 73280
----	--------------

20 CFR

220	78235
-----	-------

21 CFR

16	77019
112	77775
573	72315
862	72982, 75489
864	72315
866	73565, 75491, 75953, 77448
870	72317
872	71153, 72320
876	72715, 72984, 75493
882	71155
886	72322
888	71157
890	71159
1141	74831

Proposed Rules:

16	77058
26	77062
74	77467
173	78836
866	78265
1308	75979

22 CFR

Proposed Rules:

120	78278
121	78278

24 CFR

214	75497
-----	-------

570	78239
3280	75704
3282	75704
3285	75704
3286	75704

Proposed Rules:

5	72766
---	-------

26 CFR

1	73568, 75984
54	77586
301	75984

Proposed Rules:

1	71193, 71214, 71864, 75061, 75990, 76356, 76759, 77467
301	71214, 72348

27 CFR

Proposed Rules:

4	73050
5	73050
19	73050
24	73050
26	73050
27	73050

29 CFR

2590	77586
4044	76730

30 CFR

550	71160
-----	-------

31 CFR

100	78241
501	74832
510	75955
525	75955
526	75955
536	75955
542	75955
544	75955
546	75955
547	75955
548	72717, 75955
549	75955
550	75955
551	75955
552	75955
553	75955
555	75955
558	75955
560	75955
562	75955
569	75955
570	75955
576	75955
578	75955
579	75955
582	75955
583	75955, 78815
584	75955
585	75955
587	72717, 72718, 72719, 75955, 78245, 78247
588	75955
589	75955
590	75955
591	72986, 75955
594	75955
598	75955
599	75955
1010	72156
1032	72156

Proposed Rules:

1	76783
---	-------

32 CFR

Proposed Rules:

3	71865, 77065
---	--------------

33 CFR

100	71821, 71823, 71824, 72323, 72327, 72721, 75968, 76416, 78815
117	71184, 78818
149	76676
165	71824, 72329, 72987, 72989, 73289, 73291, 74132, 74135, 75502, 75971, 76417, 76419, 76731, 77451, 77453, 77776, 77778, 77780, 77782, 78249, 78819, 78821

Proposed Rules:

100	72348
165	73054, 73055

34 CFR

Ch. VI	76734
--------	-------

36 CFR

214	72990
251	72990

Proposed Rules:

7	75511
1191	71215

37 CFR

42	76421
----	-------

38 CFR

Proposed Rules:

4	74162
21	72351

39 CFR

3	78251
111	75973

40 CFR

52	71185, 71826, 71830, 72721, 73568, 74834, 74836, 74847, 75502, 75973, 76735, 76737, 76740, 77023, 78255
60	74135
63	73293
81	71830
84	73588
98	71838
180	72994
271	73592
300	72331
705	72336
1068	77025

Proposed Rules:

52	71230, 71237, 71872, 72353, 72770, 74165, 74171, 75517, 75524, 76013, 76442, 77467, 77786, 78837
55	73617
63	72355
84	75898
180	72775
300	72356
705	72362

41 CFR

300–3	77025
301–11	77025
301–50	77025
301–52	77025
301–70	77025

301–71.....	77025	35.....	76676	47 CFR	214.....	79005
301–73.....	77025	39.....	76676	1.....	215.....	79005
42 CFR		56.....	76676	9.....	235.....	79003
88.....	73592	76.....	76676	11.....	237.....	79013
93.....	76280	77.....	76676	14.....	252.....	79003, 79005, 79013
423.....	72998	95.....	76676	54.....		
433.....	79020	96.....	76676	63.....		
438.....	79020	105.....	76676	64.....	49 CFR	
447.....	79020	107.....	76676	73.....	571.....	76236
1007.....	76431	108.....	76676	Proposed Rules:	1002.....	76434
Proposed Rules:		109.....	76676	Ch. 1.....	Proposed Rules:	
121.....	74174	115.....	76676	1.....	571.....	76922
43 CFR		116.....	76676	54.....	595.....	76035
8360.....	72999	118.....	76676	64.....		
44 CFR		132.....	76676	77470		
Proposed Rules:		147.....	76676	90.....	50 CFR	
206.....	77786	159.....	76676	96.....	17.....	72739, 73308, 75976
45 CFR		160.....	76676	48 CFR	217.....	77972
146.....	77586	161.....	76676	201.....	300.....	73602
147.....	77586	162.....	76676	204.....	622.....	71860, 76438
170.....	72998	163.....	76676	206.....	635.....	75504, 77029
46 CFR		164.....	76676	212.....	648.....	72758, 77455, 78258
2.....	76676	167.....	76676	215.....	660.....	77033
10.....	76312	169.....	76676	217.....	679.....	71861, 72340, 73002,
31.....	76676	181.....	76676	225.....		75505, 76743, 76744, 77035,
32.....	76676	195.....	76676	242.....		77456, 78825
34.....	76676	199.....	76676	247.....	Proposed Rules:	
		401.....	76312	252.....	17.....	72362, 73330, 73512,
		402.....	76312	Proposed Rules:		76196, 77972, 78134
		Proposed Rules:		209.....	229.....	77789
		401.....	71877	212.....	622.....	72794
		541.....	77787		635.....	72796

<div>LIST OF PUBLIC LAWS</div> <div>Note: No public bills which have become law were received by the Office of the Federal Register for inclusion</div>	<div>in today's List of Public Laws.</div> <div>Last List September 24, 2024</div>	<div>Public Laws Electronic Notification Service (PENS)</div> <div>PENS is a free email notification service of newly</div>	<div>enacted public laws. To subscribe, go to https://portalguard.gsa.gov/__layouts/PG/register.aspx.</div> <div>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.</div>
--	---	---	---